Levonorgestrel

Jadelle®
75mg Implant (For Subdermal Use Only)
Hormonal Contraceptive

1. NAME OF THE MEDICINAL PRODUCT

Jadelle® without inserter 2 x 75 mg implant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The product consists of two implants.
Each implant contains:
Levonorgestrel.....75 mg
The release rate of levonorgestrel is about 100 micrograms/day at one month after insertion, declining to about 40 micrograms/day within one year, to about 30 micrograms/day within three years, and to about 25 micrograms/day within five years.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Implant

The implants are flexible, sealed, white or off-white rods, about 43 mm in length and 2.5 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Indication(s)

Contraception.
Clinical efficacy and safety have been established in women aged 18 to 40 years.

4.2 Posology and method of administration

For subcutaneous use.
Jadelle is a contraceptive method for long-term (up to five years) use (see section 4.4). The user must be informed that Jadelle implants may be removed at her request at any time.

Instructions for insertion of Jadelle implants

One Jadelle package contains two sterile implants packed in a pouch. Training is required for the insertion and removal procedures, which should preferably be done by a health care professional and the given instructions must be followed closely. The implants are inserted with the disposable sterile trocar just beneath the skin.

Important: the disposable Jadelle Trocar is for single use only! After insertion the trocar must be disposed of in an appropriate sharps container.

Strict asepsis must be observed here. The implants are inserted in the inner aspect of

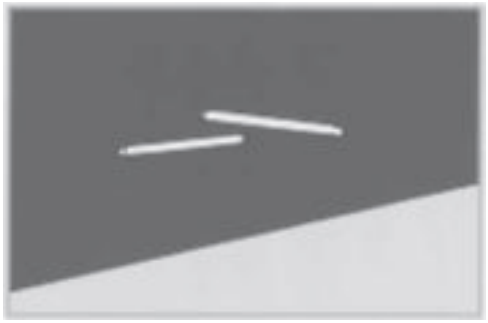
the upper left arm in right-handed women and in the right arm in left-handed women, approximately 8 cm above the fold in the elbow. Before insertion, the skin is cleaned with an antiseptic and the insertion area anaesthesized. A transverse incision of 2 mm is made in the skin with a scalpel. The implants are placed with the trocar subdermally, in the shape of a V opening towards the armpit. Proper insertion will facilitate later removal and result in minimal scarring. After insertion of the second implant, the edges of the incision are pressed together, closed with a skin closure and dressed.

Picture 1
The following equipment is needed for the insertion of Jadelle implants.

- a table for the patient to lie on, and another table or a rest for her arm
- sterile surgical cloths, a sterile tray for the equipment, sterile gloves (free of talc), antiseptic solution for the skin
- local anaesthetic, an anaesthetic needle (5–5.5 cm long) and a 5-ml syringe
- Jadelle Trocar, a scalpel with blade, tweezers
- a skin closure, gauze and compresses.

Picture 2
Ask the patient to lie down on the table with her non-dominant arm extended on a sterile cloth on the other table, at right angles to her body. The implants will be inserted subdermally through an incision, in the shape of a narrow V opening towards the armpit.

Picture 3
Clean the patient's arm with an antiseptic solution, and cover the arm with either two sterile cloths or a sterile fenestrated drape. The optimal insertion area is in the inner aspect of the upper arm, between the muscles, about 6–8 cm above the fold in the elbow.



Picture 4
Open the Jadelle pouch by pulling apart the films of the pouch and let the two implants drop on a sterile cloth. Do not touch the inside of the package or its contents with bare hands. NOTE: Always use sterile gloves or forceps when
handling the implants. If a rod is contaminated, e.g. falls on the floor, it must be disposed of. Open a new package and continue with the procedure.

Picture 5
First determine any known allergies to the anaesthetic agent or related medicinal products. Fill the syringe with about 2–4 ml of local anaesthetic. Anaesthetize the insertion area by inserting the needle just under the skin about 5 to 5.5 cm in the directions where you are planning to introduce the trocar.

Picture 6
Make a small incision of about 2 mm with the scalpel through the skin. Alternatively, the trocar may be inserted directly through the skin without making an incision with the scapel, though it is not recommended for Jadelle sine inserter.

Picture 7
The disposable Jadelle Trocar has two marks. One mark is close to the handle and it shows how far the trocar should be introduced under the skin before the loading of each implant. The mark close to the tip indicates how much of the trocar is under the skin following the insertion of the first implant. When inserting the tip of the trocar beneath the skin through the incision, avoid touching the part of the trocar that will go under the skin.

Picture 8
Once the tip of the trocar is beneath the skin, direct it along the skin so that the implants will be placed just beneath the skin. Throughout the insertion procedure, the trocar should be oriented with the bevel up. It is important to hold the trocar just beneath the skin by the tenting the skin with the trocar, because otherwise the implants may be inserted too deep and their removal is more difficult.
Advance the trocar beneath the skin about 5.5 cm from the incision to the mark in the trocar. Do not force the trocar, and if you feel any resistance, try another direction.

Picture 9
Remove the plunger when the trocar is advanced to the correct mark and load the first implant into the trocar either with fingers or tweezers.

Picture 10
Push the implant gently to the tip of the trocar with the plunger until you feel resistance. Never force the plunger.

Picture 11
Hold the plunger steady and pull the trocar cautiously back along it until it touches the handle of the plunger. It is important to keep the plunger steady and not push the implant into the tissue. Pull the trocar only up to the mark near the tip. Remove it completely only after both implants have been inserted.

Picture 12
When you can see the mark near the tip of the trocar, the implant has been released and will remain in place beneath the skin. You can check this by palpation with fingers.

Picture 13
Insert the second implant at the side of the first one to form a V shape. Follow the previous implant with your left-hand forefinger and advance the trocar along the side of the finger. This will ensure a suitable distance between the implants.
To prevent expulsions, leave a distance of about 0.5 cm between the incision and the ends of the implants. You can check their correct position by cautious palpation of the insertion area.

Picture 14
After insertion, press the edges of the incision together and close the incision with a sterile skin closure. Suturing the incision is not necessary and may even increase scarring.
IMPORTANT: after insertion, the disposable Jadelle Trocar cannot be used for further insertions. The trocar must be disposed of in an appropriate sharps container.

Picture 15
Cover the insertion area with compresses, and wrap enough gauze around the arm to ensure haemostasis. Observe the patient at the clinic for a few minutes before she is discharged.

Advise the patient to keep the insertion area dry for three days, and give her a copy of the Jadelle patient information leaflet, in which you have entered the date of insertion and the date of the first control visit. The gauze and the bandage may be removed as

soon as the incision has healed, usually after 3–5 days.

Starting the use of Jadelle implants

No preceding hormonal contraceptive use in the past month

Jadelle implants should be inserted within seven days from the onset of menstrual bleeding. If the implants are inserted at any other time, pregnancy must be reliably excluded before insertion and an additional non-hormonal contraceptive method used for at least seven days after the insertion.

Changing from a combined hormonal contraceptive (combined oral contraceptive /COC), vaginal ring or transdermal patch

Jadelle should preferably be inserted on the day after the last active tablet of previous combined oral contraceptive but at the latest on the day after the 7th day of the tablet free interval or placebo tablet. In case a vaginal ring or transdermal patch has been used, Jadelle should preferably be inserted on the day of removal of the last ring or patch of a cycle pack, but at the latest when the next application would have been due.

Changing from another progestogen-only method (minipill, injection, implant)

The woman may switch any day from the minipill, from another implant on the day of its removal, and from an injectable when the next injection is due.

Following first-trimester abortion

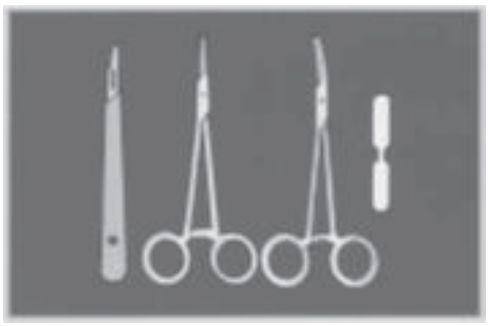
Jadelle may be inserted immediately. When doing so, no additional contraceptive measures are needed.

Following delivery or second-trimester abortion

Jadelle may be inserted immediately after childbirth or second-trimester abortion for women who are not breast-feeding. If inserted later than 21 days after childbirth, pregnancy should be reliably excluded and additional non-hormonal contraceptive precautions taken for a minimum of seven days after the insertion. Breast-feeding women should not start to use the Jadelle method earlier than six weeks after delivery.

Removal of Jadelle implants

Jadelle implants may be removed at any time for medical or personal reasons but they must be removed after five years from the insertion at the latest. The implants may be removed at any time of the menstrual cycle. Loss of contraceptive effect occurs practically immediately, and another contraceptive method should be applied unless pregnancy is desired. When starting the removal of implants, the skin is cleaned, and a local anaesthetic is infiltrated under the implant ends. A skin incision of 2-4 mm is made with a scalpel below the bottom of the V. The implants are removed using small (e.g. Mosquito) forceps. The implants should be removed very gently. This will take more time than the insertion. The implants may be nicked, cut or broken off during removal. If removal proves difficult or both implants cannot be removed, the patient should be asked to return for a second visit after the removal area has healed. A non-hormonal method of contraception should be used until both implants have been completely removed. If the patient wishes to continue using the method, a new set of Jadelle implants may be inserted through the same incision, either in the same or in the opposite direction.

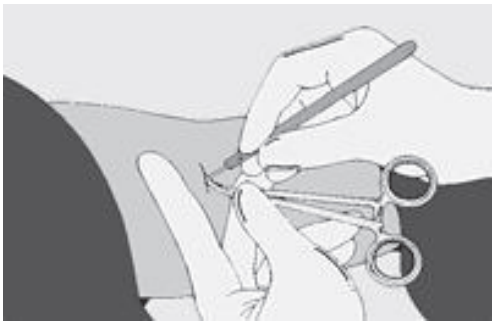


Picture 16
The following equipment is needed for removal:

- local anaesthetic, an anaesthetic needle and a syringe
- a scalpel
- two different types of forceps (Mosquito and Crile)
- a skin closure, gauze and compress

Picture 17
Locate the implants by palpation, possibly marking their position with a marker pen. If they cannot be palpated, they may be located by ultrasound or soft tissue X-ray. Inject a small amount of local anaesthetic under the ends of the implants that are closer to each other. Anaesthetic injected over the implants may obscure their position and make removal more difficult. If necessary, more anaesthetic can be given in small amounts at a time.

Picture 18
Make a 4-mm incision with the scalpel close to the ends of the implants. Keep the incision small.



Picture 19
Push each implant gently with your fingers towards the incision. When the tip is visible in the incision, grasp it with the Mosquito forceps. Use a scalpel to very gently open the tissue capsule around the implant.

Picture 20
Grasp the end of the implant with the second forceps (Crile).

Picture 21
Remove the implant gently. Repeat the procedure for the second implant.

Measure the length of the removed implants. The length of Jadelle implants is 43 mm. This will ensure that the patient has had two Jadelle implants and not other contraceptive implants.
After the procedure is completed, close the incision and bandage it as after incision. The arm should be kept dry for a few days.
Following removal, pregnancy may occur at any time.

4.3 Contraindications

Hypersensitivity to levonorgestrel or any other component of Jadelle,
undiagnosed vaginal bleeding,
diagnosed or suspected sex hormone dependent neoplasia,
presence or history of severe hepatic disease as long as liver function values have not returned to normal
benign or malignant liver tumour,
thromboembolic disease.

4.4 Special warnings and precautions for use

Warnings
Clinical trials have shown the contraceptive efficacy of Jadelle implants to decrease after the fourth year of use. Consequently, the removal of Jadelle implants and their change into new implants should be considered after four years of use, especially in women weighing over 60 kg (see 5.1). The serum levonorgestrel concentration is lower at the end of the implant use and it is inversely related to the user's body weight.

Expulsion of an implant may occur before the incision has healed if the implants have been inserted very near the skin surface or too close to the incision or when the

insertion site is infected. An expelled implant must always be replaced with a new, sterile implant.

Reports have been published on slight displacement of similar levonorgestrel implants, most of which have involved minor changes in the position of the implants. Infrequent reports on significant displacement (a few to several centimetres) have been received. Some of these cases have been associated with pain or discomfort. In the event of displacement, the removal technique may have to be modified and may involve additional incisions or visits.

Altered serum lipoprotein levels have been observed in clinical trials on Jadelle. Although statistically significant decreases in total cholesterol, HDL (high-density lipoprotein) and LDL (low-density lipoprotein) and triglycerides have been detected, all mean values have remained within the normal ranges. The long-term clinical significance of these changes has not been determined.

The effects of Jadelle on clotting factors have varied. In patients with a history of thromboembolic disease, Jadelle should only be used if other contraceptive methods are unsuitable and after careful assessment of the risk-benefit ratio. Thromboembolic and cardiovascular undesirable effects have been reported in users of other levonorgestrel implants. Cases of stroke, myocardial infarction, pulmonary embolism and deep venous thrombosis have been reported in users of other levonorgestrel implants. Patients who develop thrombotic or embolic disease should have their Jadelle implants removed (see also section ‘Large and small surgical procedures’). Thrombophlebitis and superficial phlebitis have occurred more commonly in the arm of insertion. Some cases have been associated with trauma to that arm.

Special caution should be observed in prescribing Jadelle implants for patients with recognized risk factors for or any predisposition to arterial disease.

If a sustained hypertension develops during the use of Jadelle implants, or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the use of Jadelle implants should be discontinued.

If a patient has a history of or develops focal or crescendo type migraine or exhibits worsening of such migraine during the use of Jadelle, the situation should be carefully assessed.

Contact lens wearers who develop loss of vision or changes in lens tolerance should be assessed by an ophthalmologist. The patient may be advised to stop wearing contact lenses for a while or completely.

Altered glucose tolerance and insulin sensitivity in oral glucose tests have been reported in users of Jadelle in some studies. The clinical significance of these findings is unknown but diabetic patients using Jadelle should be carefully monitored. A gain in weight is possible during the use of Jadelle.

If cholestatic hepatitis or jaundice develops in a patient with Jadelle, the implants must be removed. A mild or moderate transient rise in total serum bilirubin is usual at the start of the implant use. A slightly increased risk of cholelithiasis has been reported during the use of other levonorgestrel implants of similar type. Levonorgestrel

metabolism may be slower than normal in patients with impaired liver function.

Removal of Jadelle should also be considered in women who become significantly depressed, since the symptom may be hormone-related.Women with a history of depression should be carefully monitored and removal of Jadelle considered if clear symptoms develop.

Steroid hormones may cause some degree of fluid retention, which may result in weight gain. The use of Jadelle should be considered carefully in patients with conditions that might be aggravated by fluid retention, and their condition should be monitored closely during the use of Jadelle.

Idiopathic intracranial hypertension has been reported on rare occasions in users of levonorgestrel implants. Evidence is based on isolated reports only. This diagnosis should be considered if persistent headache and/or visual disturbances occur in a woman with Jadelle, particularly if the patient is obese or has recently gained weight. If idiopathic intracranial hypertension is diagnosed, Jadelle should be removed.

Jadelle implants affect the menstrual bleeding pattern in most women. Irregular, prolonged and intermenstrual bleeding, spotting and amenorrhea have been reported. In general, such irregularities decrease with continuing use. Significant blood loss leading to anaemia is rare, and average concentrations of haemoglobin normally rise slightly in Jadelle users.

Since some users of Jadelle experience periods of amenorrhoea, missed menstrual periods should not be relied on as the sole means of diagnosing pregnancy. A pregnancy test should be performed whenever pregnancy is suspected. Six or more weeks of amenorrhoea after a period of regular menses may indicate pregnancy. The implants must be removed if pregnancy occurs.

Ectopic pregnancy occurs rarely with levonorgestrel implants: at a rate less than 1 per 1000 woman-years. If a woman using Jadelle presents with lower abdominal pain or is found to be pregnant, she should be examined to exclude ectopic pregnancy.

Follicles develop during the use of Jadelle but their atresia may be delayed and they may continue to grow beyond the normal size. In most women, such enlarged follicles will disappear spontaneously. In rare cases, however, they may twist or rupture, causing abdominal pain. Even in the presence of symptoms, conservative management is indicated but ectopic pregnancy must be excluded. Surgical intervention is rarely warranted.
In some rare cases, autoimmune diseases such as scleroderma, LED (lupus erythematosus disseminata) or rheumatoid arthritis have been reported in users of levonorgestrel implants. No causal relationship to implants containing levonorgestrel has been established. Both during pregnancy and during the use of sex steroids, following conditions have been observed, without confirmed relationship to the use of progestogens: cholestatic icterus and/or itching, cholelithiasis, haemolytic-uremic syndrome, herpes gestationis, and hearing loss associated with otosclerosis.

Even though there is no clear causal connection between the use of oral contraceptives and breast cancer, a meta-analysis of epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women

who are currently using combined oral contraceptives (COCs). The increased risk gradually disappears during the course of 10 years after cessation of COC use. The risk of having breast cancer diagnosed in progestogen-only contraceptive users is possibly of a similar magnitude to that associated with COCs.

Precautions
Before initiating or reinstituting treatment, a complete medical and family history should be taken. Blood pressure should be measured and a physical examination should be performed, guided by the contraindications and warnings and precautions for use. The woman should also be instructed to carefully read the user leaflet and to adhere to the advice given and to contact her physician if any problems occur at the insertion area. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.
The insertion area should be examined at every control visit. If undiagnosed, persistent or recurrent vaginal bleeding occurs, appropriate measures should be taken to rule out malignancy.Women with a family history of breast cancer or who have benign breast nodules or mastopathy should be monitored with particular care.
Women should be advised that Jadelle implants do not protect against HIV infections (AIDS) and other sexually transmitted diseases.

Large and small surgical procedures
Jadelle implants do not contain oestrogen and, therefore, the use of Jadelle, as well as of other similar contraceptives, may usually be continued during surgical procedures. However, if a risk of thrombosis exists, consideration should be given to appropriate prophylactic measures. Due to a risk of thromboembolism, the removal of implants may be considered either in connection with surgery or with prolonged immobilization for some other reason.

Instructions for the patient
The package contains a patient information leaflet to facilitate explaining the characteristics of Jadelle to patients. A copy of the leaflet should be given to each patient. The advantages and disadvantages of Jadelle, other methods of contraception and of not using any contraceptive method should be explained thoroughly to the patient. In addition, information should be given on implant insertion and removal.

4.5 Interaction with other medicinal products and other forms of interaction

4.5.1 Effects of other medicinal products on Jadelle

Interactions can occur with drugs that induce microsomal enzymes, which can result in increased clearance of sex hormones and which may lead to changes in the uterine bleeding profile and/or contraceptive failure.
Women on treatment with any of these drugs should temporarily use a barrier method in addition to Jadelle or choose another method of contraception. The barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation.

Substances increasing the clearance of levornorgestrel (diminished efficacy of Jadelle by enzyme-induction), e.g.:
Phenytoin, barbiturates, primidone, carbamazepine, rifampicin, efavirenz, and possibly also oxcarbazepine, topiramate, bosentan, felbamate, griseofulvin and products containing St. John's wort.
Enzyme induction can already be observed after a few days of treatment.
Maximal enzyme induction is generally seen within a few weeks. After the cessation of drug therapy enzyme induction may be sustained for about 4 weeks.
Jadelle users should be warned of the possibility of decreased contraceptive efficacy when using medicinal products exhibiting enzyme-inducing activity such as those mentioned above: Breakthrough bleeding and unintended pregnancies have been reported.
Substances decreasing the clearance of levonorgestrel (enzyme inhibitors)
Strong and moderate CYP3A4 inhibitors such as azole antifungals (e.g. itraconazole, voriconazole, fluconazole), verapamil, macrolides (e.g. clarithromycin, erythromycin), diltiazem and grapefruit juice can increase plasma concentrations of the progestin.
Substances with variable effects on the clearance of levonorgestrel, e.g.:
When co-administered with sex hormones, many HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors can increase or decrease plasma concentrations of the progestin (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir, nevirapine, efavirenz] or increase [e.g., indinavir and atazanavir/ritonavir, etravirene]).
These changes may be clinically relevant in some cases.

4.5.2 Effects of Jadelle on other medicinal products
Jadelle may affect the metabolism of other medicinal products. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporin) or decrease (e.g. lamotrigine).
Note: The prescribing information of concomitant medications should be consulted to identify potential interactions.

4.5.3 Other forms of interaction
Laboratory tests
The use of contraceptive steroids may influence the results of certain laboratory tests.
Jadelle implants may have the following effects on the results of some endocrine laboratory tests:
1. Reduce the concentration of SHBG (sex hormone binding globulin)
2. Decrease thyroxine concentration in serum and elevate the values in triiodothyronine binding test.

4.6 Pregnancy and lactation
The implants must be removed if pregnancy occurs during the use of Jadelle. Animal studies have shown that very high doses of progestogenic substances may cause masculinization of female foetuses. The results of most epidemiological studies to date with relevant inadvertant foetal exposure to combinations of oestrogens and progestogens indicate no teratogenic or foetotoxic effect. No studies are available on the

effect of Jadelle during or prior to pregnancy.
Levonorgestrel passes over into milk but epidemiological studies to date have not revealed serious adverse effects on the child. Levels of levonorgestrel obtained with Jadelle do not affect the quality or quantity of breast milk. Breast-feeding mothers are, however, advised not to start the use of Jadelle until six weeks post partum.

4.7 Effects on ability to drive and use machines
No effects on ability to drive and use machines have been observed.

4.8 Adverse Effects
The following undesirable effects have been reported during clinical trials with Jadelle:
Very common undesirable effects (occurring in more than 10% of users):
Disturbance of menstrual bleeding patterns, such as frequent, irregular or prolonged menstrual bleeding, spotting, oligomenorrhoea or amenorrhoea, are the most common undesirable effects, occurring in the majority of users during the first year. 14% of users discontinued the use of Jadelle because of bleeding pattern disturbances during five years. Other very common undesirable effects are: headache, nervousness, dizziness, nausea, cervicitis, vaginal discharge, genital pruritus, pelvic pain, breast pain, weight gain.

Organ system	Very common undesirable effects >1/10	Common undesirable effects >1/100, <1/10	Uncommon undesirable effects >1/1000, <1/100	Rare undesirable effects >1/10000, <1/1000
Psychiatric		mood changes, depression, changes in libido, dyspareunia		
Nervous system	headache, nervousness, dizziness	migraine		
Cardiac		palpitation, chest pain		
Vascular		hypertension, varicose veins		
Respiratory		dyspnoea		
Gastrointestinal	nausea	abdominal discomfort		
Hepato-biliary		rise in total serum bilirubin		
Skin		acne, contact dermatitis, alopecia, hypertrichosis,		

		rash, pruritus, skin discolouration		
Renal and urinary		urinary tract symptoms		
Reproductive system and breast	Disturbance of menstrual bleeding patterns, such as frequent, irregular or prolonged menstrual bleeding, spotting, oligomenorrhoea or amenorrhoea, cervicitis, vaginal discharge, genital pruritus, pelvic pain, breast pain	vaginitis, ovarian cysts, benign breast nodules, breast discharge		
General disorders and administration site	weight gain	itching near the insertion site, general pain, fatigue, backpain, weight loss	bruising at insertion site, infection at insertion site	expulsion of implant, arm pain, numbness, tingling and scarring, difficulty in removal of the implant, ulnar nerve damage associated with removal of the implant, hyperpigmentation over the implant site

Expulsion or migration of Jadelle may be possible (see also section 4.4).
On rare occasions, ectopic pregnancies have been reported (see also section 4.4 Special warnings and precautions for use).
In users of similar levonorgestrel implants in various countries, limited blistering, ulceration or sloughing have been observed rarely.
During the use of other levonorgestrel implants of similar type, very rare cases of cholestatic hepatitis, jaundice, bilirubinemia and thromboembolic complications have been reported(see also section 4.4).

The occurrence of chloasma has been reported with the use of other levonorgestrel implants.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

There is no experience of overdose with Jadelle.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: progestogens, levonorgestrel
ATC code: G03AC03
The active ingredient in Jadelle implants, levonorgestrel, is a synthetic progestogen. The levonorgestrel released from the implants has been shown to affect ovarian function in various ways, ranging from absence of follicular and luteal activity through normal follicular activity but deficient luteal activity to normal ovulatory patterns. Levonorgestrel causes thickening of the cervical mucus, thus preventing passage of spermatozoa into the uterus. It also suppresses the endometrium and may prevent implantation of the blastocyst.
The contraceptive efficacy of Jadelle was studied in clinical multicentre trials involving 1393 women observed for 4657 woman-years. 525 women completed five years of use. The Pearl index during five years was 0.17 per 100 woman-years (95% confidence interval 0.04–0.30). During the fifth year, the annual Pearl index was 0.84 per 100 woman-years (95% confidence interval 0.09–1.57). The annual pregnancy rate per 100 users was 0.1 ± 0.1 at one, two and three years, 0.0 ± 0.0 at four years, and 0.8 ± 0.5 (SE) at five years. Regarding the different weight groups, the annual pregnancy rate during year 5 was 0.9 ± 0.9 per 100 users weighing less than 50 kg, 0.5 ± 0.5 per 100 users weighing 50–59 kg,
1.1 ± 0.7 per 100 users weighing 60–69 kg, and 1.1 ± 1.1 per 100 users weighing 70 kg or more. In all women with body weight of 60 kg or more, the annual pregnancy rates per 100 users were 0.2 ± 0.2 during year 1, 0.2 ± 0.2 during year 2, 0.3 ± 0.3 during year 3, 0.0 ± 0.0 during year 4, and 1.1 ± 0.6 during year 5.
After removal of the implants, women return quickly to their normal fertility. When women had Jadelle implants removed for planned pregnancy, 45% became pregnant within three months and 86% within a year.
The efficacy of Jadelle does not depend on patient compliance.

5.2 Pharmacokinetic properties

The only active ingredient in Jadelle is levonorgestrel, a progestogen. The implants are inserted subdermally.

Absorption
Levonorgestrel is released from the implants directly into tissue fluid. Maximum serum levonorgestrel concentrations of approximately 772 pg/ml are reached 48 hours after insertion. After the initial phase, levonorgestrel concentrations decline to 435 pg/ml within one month, 355 pg/ml within six months, 341 pg/ml within one year, and 277 pg/ml within five years.
Distribution
Serum levonorgestrel concentrations are inversely related to body weight; the difference is approximately twofold between women weighing 50 and 70 kg. However, due to the great variation in serum levonorgestrel concentrations and in individual response, serum concentrations alone are not predictive of the risk of pregnancy in an individual woman. In Jadelle implant users, serum levonorgestrel concentrations are substantially below those observed in women taking oral contraceptives containing levonorgestrel. In serum, levonorgestrel is mainly bound to sex hormone binding globulin (SHBG). Levonorgestrel lowers SHBG concentrations within a few days, reducing the total serum levonorgestrel concentrations.
Biotransformation
Levonorgestrel (LNG) is extensively metabolized. The most important metabolic pathways are the reduction of the Δ4-3-oxo group and hydroxylations at positions 2α, 1β and 16β, followed by conjugation. CYP3A4 is the main enzyme involved in the oxidative metabolism of LNG. The available in vitro data suggest that CYP mediated biotransformation reactions may be of minor relevance for LNG compared to reduction and conjugation.
Elimination
There is wide interindividual variation in the metabolic clearance rate. This is believed to be the reason for the wide variation in the serum levonorgestrel levels in various users. The elimination half-life of levonorgestrel is 13 to 18 hours. Levonorgestrel and its metabolites are primarily excreted in the urine (40 to 68%) and partly in faeces (16 to 48%). After removal of the implants, serum levonorgestrel concentrations decrease below detection limit within 5 to 14 days.

5.3 Preclinical safety data
The toxicity profile of levonorgestrel is well-established and reveals no particular human health risks beyond those discussed in other sections of the SmPC.
Mutagenicity and biocompatibility testing gave no indication of genotoxicity or unacceptable local tolerance of levonorgestrel or the non-active polymeric components of Jadelle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Polydimethyl siloxanes
Colloidal anhydrous silica
6.2 Incompatibilities
Not applicable

6.3 Shelf life
5 years
6.4 Special precautions for storage
Store at temperatures not exceeding 30°C.
6.5 Nature and contents of container
One (1) set contains two (2) implants in peelable film bag (White side: Adhesive coated nonwoven material of Polyethylene (PE) and Transparent side: Polyethylene terephthalate/Polyethylene [PET/PE])
6.6 Instructions for use/ handling
Box of 10 sets
Information on insertion and removal is provided in section 4.2.

7. DATE OF REVISION OF TEXT
January 2016

If you want to report a product complaint or side effect, please contact your healthcare professional or the Philippine FDA at adr@fda.gov.ph
Inquiries can also be directed to:
Bayer Philippines, Inc.
Taguig City, Philippines
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Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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Package Leaflet: Information for the user

Levonorgestrel

Jadelle®
75mg Implant (For Subdermal Use Only)
Hormonal Contraceptive
Without Inserter

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Jadelle implants are and what they are used for

Jadelle implants are used for the prevention of pregnancy (contraception). The implants consist of two thin, flexible rods made of a rubber-like material, that are inserted by a minor surgical procedure just beneath the skin on the inside of your upper arm.

The implants slowly release a small amount of the hormone levonorgestrel, which is one of the active ingredients in many oral contraceptives. Jadelle implants are long-acting and are effective for up to five years. Immediately after insertion, low doses of the hormone start to be released continuously into your body.

Jadelle implants work by a combination of factors. The most important of these are prevention of regular egg release and thickening of the cervical mucus, making it more difficult for sperm to reach the egg.

2. What you need to know before you use Jadelle implants

General notes

Before you decide to use Jadelle implants or any other contraceptive method, you should compare it to other available methods. If you want to learn more about other methods, ask your doctor or nurse. One of these other methods may be better for you than Jadelle implants. Each woman who considers using Jadelle implants should understand the benefits and risks of using this contraceptive method compared with other methods. This leaflet will give you much of the information you will need to make this decision but you will still need to discuss the matter thoroughly with your doctor. You should discuss the information provided in this leaflet, when choosing whether to use Jadelle implants and on check-up visits. Follow your doctor's advice with regard to check-ups while using Jadelle implants.

Some women should not use Jadelle implants. To find out whether you are one of them, talk to your doctor or nurse and read the sections entitled: "Do not use Jadelle implants" and "Warnings and precautions".

Some women who use Jadelle implants will experience side effects. You should know the warning signs. To learn about them, talk to your doctor or nurse and read the sections below entitled "Warnings and precautions" and "Possible side effects".

Contraceptive effectiveness of Jadelle implants
Jadelle implants are among the most effective reversible contraceptive methods. However, no contraceptive is 100 percent effective. The average annual pregnancy rate for Jadelle implants over a 5-year period is less than 1%. This means less than one pregnancy for every 100 women during the first year of use. After the 5th year of use, the contraceptive efficacy decreases, and consequently Jadelle implants must not be used for more than 5 years.

Protection against HIV infection or other sexually transmitted diseases
Jadelle implants do not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Do NOT use Jadelle implants if you:

- are allergic to levonorgestrel or any of the other ingredients in Jadelle implants (listed in section 6)
- have abnormal vaginal bleeding
- have, or are suspected of having, breast cancer or cancer of the lining of the womb
- have, or have ever had, severe illness involving your liver, as long as your liver is not working properly again as judged by laboratory
- have, or have ever had, a liver tumour (benign or malignant)
- have a blood clot in a blood vessel (thrombosis) in, for instance, your leg, lung or eye.

Warnings and precautions

Talk to your doctor before using or while you are using Jadelle implants, if any of the following symptoms occur:

- migraines or increase in the frequency of migraine attacks
- persistent headaches or problems with vision, particularly if you are overweight or have recently gained weight

- sudden headaches or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg
- pain in the calf of the leg or unusual swelling of arms or legs
- sharp pain in the chest or sudden difficulty in breathing, or coughing blood
- unbearable pain or a feeling of pressure in the chest
- severe abdominal pain or tenderness in the abdominal area
- suspect you may be pregnant
- heavy vaginal bleeding
- skin or eyes become yellow
- lump or lumps in the breast
- pain, pus or bleeding at the insertion site of the implants
- sleeping problems, weakness, lack of energy, tiredness or mood swings
- implant is expelled
- fluid retention.

If you, or someone in your family, has certain diseases, you must discuss with your doctor if you should have the implants. Tell the doctor if you:

- have had an ectopic pregnancy (see section on "Pregnancy, breast-feeding and fertility")
- or someone in your family has a history of formation of blood clots (thrombosis) or a blood clotting (coagulation) disorder, stroke, heart attack, high blood pressure, very high lipid or cholesterol levels or coronary artery disease (see section "Blood clots (thrombosis)")
- have or have had migraines or frequent headaches
- are breast-feeding
- have or have had a lump or lumps in your breast, mastopathy or an abnormal mammogram (breast X-ray) or someone in your family has had breast cancer
- have problems with your gall bladder, liver disorders or a kidney disease
- have diabetes
- have depression
- have impaired hearing due to otosclerosis
- have had itchy, red hives or small bumps (herpes gestationis) during pregnancy.

Your doctor may decide that you will be able to use Jadelle implants, even if any of the above applies to you.

Blood clots (thrombosis)

As with oral contraceptives, there have been reports of blood clots, heart attacks and strokes in connection with the use of levonorgestrel implants.

If you develop a clot, for instance in your leg, lung or eye, Jadelle implants must be removed.

If you are bedridden after **surgery**, or have limited movement for a long time because of an illness or an accident, the risk of blood clots may increase. In that case, your doctor may decide to remove the Jadelle implants.

Blood pressure

Even though studies have not shown a considerable increase in blood pressure in users of Jadelle implants, blood pressure may still increase in some women. You should therefore have your blood pressure checked regularly whilst the implants are present.

If your blood pressure increases consistently during the use of Jadelle implants, or if your blood pressure increases significantly and cannot be controlled adequately with blood pressure medication, your Jadelle implants should be removed.

Breast cancer

Do not use the implants if you have, or are suspected of having, breast cancer. Users of combined oral contraceptives have been found to have a slightly increased (1.24 times the normal) risk of breast cancer. The risk of having breast cancer diagnosed in progestin-only contraceptive users, such as Jadelle, is possibly of a similar magnitude to that associated with combined oral contraceptives.

If you have benign lumps in your breast, fibrous (tough) breast tissue or an abnormal mammogram, or if you have a family history of breast cancer, your doctor should follow your condition carefully.

Increased pressure around the brain (intracranial pressure)

Increased pressure around the brain has been reported rarely in users of levonorgestrel implants. Contact your doctor if you experience frequent, severe or persistent headaches or have problems with your vision.

Enlarged ovarian follicles (ovarian cysts)

These may occur in some women with Jadelle implants. Such follicles will be detected in a physical examination and usually disappear on their own. In rare cases, however, they may twist or rupture, causing abdominal pain, and may require surgery. If you feel any pain or discomfort contact your doctor.

Children and adolescents

The safety and effectiveness of Jadelle implants have not been established in females below 18 years.

Other medicines and Jadelle implants

Always tell your healthcare professional if you are taking, have recently taken or might take any other medicines. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist from whom you get the medicine) that you are using Jadelle. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long (see section on “Extra contraceptive precautions”), or, whether the use of another medicine you need must be changed.

Some medicines

- can have an influence on the blood levels of Jadelle
- can make Jadelle **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include:

- medicines used for the treatment of:
- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin)
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, e.g. efavirenz, nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir, nevirapine, indinavir and atazanavir/ritonavir, etravirene).
- fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole).
- pulmonary artery hypertension (e. g. bosentan)
- bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
- certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)

Mid-cycle bleeding and unintended pregnancies have been reported. You need to take additional reliable non-hormonal contraceptive precautions such as condoms while you are taking the other medicine and for **28 days** afterwards. Read carefully the section on "Extra contraceptive precautions".

In case you have a long-term treatment using the medicines mentioned above, Jadelle implants should be removed and should use non-hormonal contraception instead.

In case you have a long-term treatment using the medicines mentioned above, you should consider using another method of contraception instead of Jadelle implants.

- o the herbal remedy St. John's wort
- o grapefruit juice

Jadelle may **influence the effect** of other medicines. Accordingly, the concentration of these other medicines in the blood and tissues may either increase (e. g. cyclosporine, a medicine used to prevent rejection of transplanted organs) or decrease (e. g. lamotrigine, a medicine used to treat epilepsy).

Laboratory tests

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are using Jadelle implants because these can affect the results of some tests.

Pregnancy, breast-feeding and fertility

Pregnancy
Jadelle implants must not be used during an existing or suspected pregnancy.

Ectopic pregnancy has sometimes occurred in users of other levonorgestrel implants.
Symptoms of ectopic pregnancy include:

- spotting (a small amount of blood loss)

- cramping abdominal pain

These usually begin shortly after the first missed period. Contact your doctor if you miss a period or have abdominal pain.

If, after the insertion of the implants, you first have a regular bleed and then your period is more than 6 weeks late, you should make sure that you are not pregnant.

If you become pregnant with Jadelle implants in place, you must have the implants removed. There are no studies available for Jadelle regarding an effect on the baby if used before or during pregnancy. However, contraceptive pills containing levonorgestrel used prior or during pregnancy have not caused harmful effects on the baby.
If you want to become pregnant Jadelle implants can be removed at any time by your healthcare professional (see section 3 "When should Jadelle implants be removed?"), after which pregnancy may be possible.

Breast-feeding
If you are breast-feeding and want to use these implants, you should discuss this with your doctor. Small amounts of levonorgestrel (the hormone in Jadelle implants) will be excreted in breast milk. Studies have not shown any significant effects on the growth or other development of breast-fed babies whose mothers used other levonorgestrel implants from the sixth week after childbirth. However it is not known if levonorgestrel is found in breast milk in the first 6 weeks after giving birth.

Fertility
Your usual level of fertility will return after the implants are removed.

Driving and using machines

Jadelle implants have no influence on ability to drive or use machines.

3. How to use Jadelle implants

Jadelle implants are different from other contraceptive methods. They must be inserted and removed by a healthcare professional familiar with the minor surgical procedure. Some doctors have more experience than others in inserting and removing these implants. Discuss with your doctor or nurse to find out whether he/she is familiar with the insertion and removal of Jadelle implants and feels that he/she masters the procedures.

Before inserting the implants your doctor/healthcare professional will:

- ask you about your medical history
- perform a physical examination
- make sure that you are not pregnant.

Placement of Jadelle implants

Jadelle implants should be placed within seven days from the start of your menstrual bleed (your monthly period). In this case you will not need to take any additional contraceptive precautions.

If insertion is done after the 7th day (from the first day of bleeding) you will have to use other non-hormonal contraception e.g. condoms for at least the next 7 days. Read carefully the section on "Extra contraceptive precautions".

Changing from a combined hormonal contraceptive (combined oral contraceptive /COC), vaginal ring or transdermal patch)

Jadelle implants should preferably be inserted on the day after you have taken the last active tablet of your combined oral contraceptive but at the latest on the day after the 7th day of the tablet free interval or placebo tablet.

If you have previously used a vaginal ring or a transdermal patch, Jadelle should preferably be inserted on the day of removal of the last ring or patch of a cycle pack, but at the latest when the application of the next ring or patch would have been due.

Changing from another progestagen-only method (minipill, injection, implant) or from a progestagen-releasing intrauterine system (IUS)

Jadelle implants may be inserted

- on any day if you have previously taken the minipill,
- on any day once your previous implant or IUS has been removed,
- when the next injection would have been due.

Use of Jadelle after giving birth, or after miscarriage or abortion

- If you have given birth but are not breast-feeding, Jadelle may be inserted immediately after childbirth.
- If Jadelle is inserted within 3 weeks of delivery, you will not need other contraceptive precautions.
- If Jadelle is inserted later than 3 weeks after giving birth, your doctor will make sure that you are not pregnant, and you must use other non-hormonal methods of contraception for a minimum of 7 days after the insertion.
- If you have just had a miscarriage or an abortion the implants can be inserted immediately. Your doctor will tell you more about this.

Procedure

1. The doctor/healthcare professional will insert the two thin Jadelle implants just beneath the skin on the inside of your upper arm. If you are right-handed, usually your left arm is used, and if you are left-handed, your right arm is used.

2. A small cut will be made to insert the implants, to do this a local anaesthetic will be used at the insertion site.

3. The implants are placed underneath the skin, one at a time, with a separate instrument (trocar). Since the insertion site is anaesthetised, you should not feel any pain.

4. After the procedure, the insertion site will be closed with skin tape and bandaged. Keep the wound dry and bandaged for 3 days. Do not bruise the insertion site during this time or lift anything heavy with that arm.

There may be some discolouration, bruising and swelling at the implant site for a few days after the insertion but these should not interfere with your normal activities. Occasionally, an infection may occur or there may be temporary pain, discomfort or itching.

The following skin reactions have been reported in connection with the insertion of other similar levonorgestrel implants:

- scarring, blistering, shedding of skin, ulceration, tingling and numbness.

Talk to your doctor if you are worried – see also section 4.

Expulsion and displacementof implant

It is possible that an implant is expelled before the incision in your arm has healed, especially if the implants have been inserted very near the skin surface or too close to the incision or if the implant site is infected. If this happens contact your doctor because an expelled implant must always be replaced with a new, sterile implant.

You also need to take additional reliable non-hormonal contraceptive precautions such as condoms, until you have seen your doctor. Read carefully the section on “Extra contraceptive precautions”.

The implant may move position in your arm. This has been reported infrequently, however you may feel pain or discomfort. If you feel the implant has moved, contact your doctor.

Extra contraceptive precautions

If you need extra contraceptive precautions

- use reliable non-hormonal contraception, such as condoms or
- do not have sex.

Do not use the rhythm or temperature method as additional contraceptive precautions. Changes in body temperature and cervical mucus that normally take place during the menstrual cycle may not occur during the use of Jadelle implants.

When you should see your healthcare professional

After some time has elapsed from the insertion of the implants, your doctor/healthcare professional may want to check the implant site.

As with other hormonal contraceptives, you will need regular check-ups while you are using Jadelle implants. Your doctor will tell you how often to go for check-ups.

When should Jadelle implants be removed?

You can decide to have your Jadelle implants removed at any time, after which pregnancy is possible. Therefore, if you do not want to have another set of Jadelle implants inserted and do not wish to become pregnant, you must start using another method of contraception immediately.

Jadelle implants **must be removed at the end of 5 years**. Do not put off removal after the 5 years have elapsed, as the implants will start to lose their effectiveness after that time. If you cannot see a doctor in time to have them removed at the end of the fifth year, you must take additional contraceptive precautions and have the implants removed as soon as possible. Read carefully the section on “Extra contraceptive precautions”.

If you want to continue using the implants, a new set can be inserted when the existing implants are removed.

If you weigh over 60 kg, your doctor may recommend that the implants are removed and replaced after 4 years of use rather than wait for the 5th year.

Removal procedure for Jadelle implants

The removal of Jadelle implants may be more difficult than their insertion. It may take longer and involve more pain. It may leave scars – a risk that does not exist with most other contraceptive methods.

1. As the implants are located beneath the skin on the inside of your upper arm, they must be removed by a doctor. Do not try to remove them yourself.
2. The implant site will be anaesthetised and a small cut will be made in the skin.
3. After the removal, keep the wound clean, dry and bandaged for 3 to 5 days or until the skin has healed.

Bruising may occur at the site following removal. If the implants have been placed too deep, they may be more difficult to remove.

If both implants cannot be removed at the first attempt, you will need to see the doctor again for a new attempt. You must use another method of contraception until both implants have been removed.

In cases where the removal of the implants has been difficult, there have been reports of pain, numbness, tingling and scarring in the upper arm.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most frequently reported side effect is:

- irregularity of menstrual bleeding where periods may become prolonged (taking more days than usual), lighter or heavier, more frequent or less frequent, or spotting may occur between periods. In some women, periods may stop altogether.

Such bleeding irregularities occur in the majority of users during the first year and often reduce with continuing use of Jadelle implants. Despite the increased number of bleeding days, monthly blood loss is usually no greater than from normal menstruation.

Blood sugar and fat (lipid) levels may also be altered during the use of these implants. Patients with diabetes or disorders of lipid metabolism should therefore be monitored closely during the use of these implants. Blood bilirubin levels reflecting liver function may rise at the start of using the implants.

If you wear **contact lenses**, you may have vision changes or you may no longer be able to wear your lenses. If this happens, you should contact your doctor.

The following side effects have been reported in clinical studies:

Very common side effects: may affect more than 1 in 10 woman

- headache, nervousness, dizziness
- feeling sick (nausea)
- cervical inflammation, vaginal discharge, itching of the external genitals, lower abdominal pain, breast pain
- weight gain

Common side effects: may affect up to 1 in 10 woman
- mood swings, depression, decreased sexual drive, pain during sexual intercourse
- migraine
- palpitation, chest pain
- high blood pressure, varicose veins
- difficulty in breathing
- abdominal discomfort
- bilirubin, which is produced by your liver, may rise (this will show up in blood tests)
- acne, irritation of the skin *(contact dermatitis)*, hair loss, excessive hairiness, rash, itching, skin discolouration
- urinary tract symptoms
- vaginal inflammation, ovarian cysts, benign breast lumps, breast discharge
- pain or itching at the implant site, pain in general, tiredness, back pain
- weight loss

Uncommon side effects: may affect up to 1 in 100 people
- bruising or infection at the implant site

Rare side effects: may affect up to 1 in 1,000 people
- expulsion of implant (see section 3"Expulsion and displacement of implant"), arm pain, numbness, tingling and scarring, difficulty in removal of the implants, nerve damage in the arm associated with removal of the implant, darkening of the skin over the implant site

On rare occasions, ectopic pregnancies have been reported (see section 2 "Pregnancy, breast-feeding and fertility").

Darkened skin areas (hyperpigmentation) occurred in users of other levonorgestrel implants.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jadelle implants

Store at temperatures not exceeding 30°C
Keep this medicine out of the sight and reach of children.

Jadelle implants must not be inserted after the expiry date printed on the packaging. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Jadelle implants contains

The product consists of two implants to be inserted subdermally.
The **active substance** is levonorgestrel. Each implant contains 75 mg levonorgestrel.
The **other ingredients** are: polydimethylsiloxane, anhydrous colloidal silica.

What Jadelle implants looks like and contents of the pack

The set contains two flexible, sealed, white or off-white rod-like implants, about 43 mm in length and 2.5 mm in diameter.
The two sterile implants are packed into a bag made from specialist plastic/woven material. This pack is for single use only.

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If you want to report a product complaint or side effect, please contact your healthcare professional or the Philippine FDA at adr@fda.gov.ph
Inquiries can also be directed to:
Bayer Philippines, Inc.
Taguig City, Philippines
E-mail: medinfoph@bayer.com
drugsafety.philippines@bayer.com

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℞

Patient Reminder Card for Jadelle sine inserter 2 x 75 mg implants

Period of use: 5 years

Batch No.

The implants were inserted by:

_____

Telephone number of the doctor or nurse:

_____

Date:

_____

Next visit: Remarks:

_____

_____

_____

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_____

_____

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_____

Polyeto ng Impormasyon ng Pasyente

Levonorgestrel

Jadelle®
75mg Implant (For Subdermal Use Only)
Pampigil sa pagbubuntis

Maingat na basahin ang lahat ng nasa *leaflet* na ito bago ninyo simulang gamitin ang gamot na ito dahil naglalaman ito ng mahalagang impormasyon para sa inyo.
- Itago ang *leaflet* na ito. Maaaring kailanganin ninyong basahin itong muli.
- Kung kayo ay may anumang mga karagdagang katanungan, magtanong sa inyong doktor o *nurse*.
- Ang gamot na ito ay inireseta para sa inyo lamang. Huwag itong ibibigay sa iba.
- Kung magkakaroon kayo ng anumang mga di-kanais-nais na epekto o *side effects,* kausapin ang inyong doktor o *nurse*. Kabilang dito ang anumang posibleng *side effects* na hindi nakalista sa *leaflet* na ito.

Ano ang nilalaman ng *leaflet* na ito

1. Ano ang Jadelle *implants* at ano ang pinaggagamitan ng mga ito

Ang Jadelle *implants* ay ginagamit para hadlangan ang pagbubuntis (pagdadalang-tao). Ang *implants* ay binubuo ng dalawang manipis, nababaluktot na parang mga maliliit na baras *(flexible rods)* na gawa sa materyales na parang goma, na inilalagay sa pamamagitan ng isang di-maselan na operasyon sa ilalim lamang ng balat sa loob ng bandang itaas ng braso ninyo.

Ang *implants* ay dahan-dahang nagpapakawala ng kaunting *hormone* na levonorgestrel, na isa sa mga aktibong sangkap sa maraming iniinom na mga pampigil sa pagbubuntis. Ang Jadelle implants ay may pangmatagalang bisa at epektibo hanggang sa limang taon. Pagkalagay pa lamang, ang mababang mga dosis ng *hormone* ay kaagad na magsisimulang pakawalan nang tuluy-tuloy sa katawan ninyo.

Ang Jadelle *implants* ay gumagana sa pamamagitan ng kumbinasyon ng mga dahilan *(factors)*. Ang pinakaimportante sa mga ito ay ang paghadlang sa paglalabas ng itlog ng babae at pagpapakapal sa *mucus* sa *cervix*, kaya nagiging mas mahirap para sa semilya *(sperm)* na makarating sa itlog.

2. Ano ang kailangan ninyong malaman bago ninyo gamitin ang Jadelle *implants*

Mga pangkalahatang paunawa

Bago kayo magdesisyon na gumamit ng Jadelle *implants* o anumang ibang paraan ng pampigil sa pagbubuntis, dapat ninyo itong ihambing sa ibang mga paraang maaaring gamitin. Kung gusto ninyong mas maraming malaman tungkol sa ibang mga paraan, magtanong sa inyong doktor o *nurse*. Ang isa sa ibang mga paraang ito ay maaaring mas mabuti para sa inyo kaysa Jadelle *implants*. Dapat maunawaan ng bawat babaeng mag-iisip na gumamit ng Jadelle *implants* ang mga pakinabang at mga panganib sa paggamit ng paraang ito ng pampigil sa pagbubuntis kung ihahambing sa ibang mga paraan. Ang *leaflet* na ito ay magbibigay sa inyo ng karamihan sa impormasyong kakailanganin ninyo para gawin ang desisyong ito pero kakailanganin pa rin ninyong talakayin nang husto ang bagay na ito sa inyong doktor. Dapat ninyong talakayin ang impormasyong ibinibigay sa *leaflet* na ito, kapag pumipili kung gagamitin ang Jadelle *implants*, at sa mga pagbisita para sa *check-up*. Sundin ang payo ng inyong doktor tungkol sa mga *check-up* habang gumagamit ng Jadelle *implants*.

Ang ilang mga babae ay hindi dapat gumamit ng Jadelle *implants*. Para malaman kung isa kayo sa kanila, kausapin ang inyong doktor o *nurse* at basahin ang mga seksiyong may pamagat na: "Huwag gumamit ng Jadelle *implants*" at "Mga babala at mga pag-iingat ".

Ang ilang babaeng gumagamit ng Jadelle *implants* ay makakaranas ng *side effects*. Dapat ninyong malaman ang mga senyales na nagbabababala. Para malaman ang tungkol sa mga ito, kausapin ang inyong doktor o *nurse* at basahin ang mga seksiyon sa ibaba na may pamagat na "Mga babala at mga pag-iingat" at "Posibleng *side effects*".

Bisa ng Jadelle *implants* sa pagpigil sa pagbubuntis
Ang Jadelle *implants* ay kabilang sa pinakamabisang mga paraan ng pampigil sa pagbubuntis na maaaring maibalik sa dati *(reversible)*. Gayunman, walang pampigil sa pagbubuntis na 100 porsiyento ang bisa. Ang karaniwang *(average)* taunang dalas ng pagbubuntis para sa Jadelle *implants* sa loob ng 5-taong panahon ay kulang sa 1%. Ang ibig sabihin nito, kulang sa isang pagbubuntis para sa bawat 100 babae sa loob ng unang taon ng paggamit. Pagkaraan ng ika-5 taon ng paggamit, ang bisa sa pagpigil sa pagbubuntis ay humihina, at dahil dito, ang Jadelle *implants* ay hindi dapat gamitin nang higit sa 5 taon.

Proteksiyon laban sa impeksiyon ng HIV o ibang mga sakit na nailipat sa pamamagitan ng pakikipagtalik
Ang Jadelle *implants* ay hindi nagbibigay ng proteksiyon laban sa impeksyon ng HIV (AIDS) o ibang mga sakit na nailipat sa pamamagitan ng pakikipagtalik.

HUWAG gagamit ng Jadelle *implants* kung kayo ay:

- may *allergy* sa levonorgestrel o anumang ibang mga sangkap ng Jadelle *implants* (nakalista sa seksiyon 6)
- may abnormal na pagdurugo sa *vagina*
- mayroon, o pinagsususpetsahang mayroon, na kanser sa suso o kanser ng *lining* ng bahay-bata *(womb)*
- mayroon, o kahit kailan ay nagkaroon, ng matinding pagkakasakit na may kinalaman sa inyong atay, hangga't ang atay ninyo ay hindi muling gumagana sa wastong paraan, sang-ayon sa paghusga ng laboratoryo
- mayroon, o kahit kailan ay nagkaroon, ng tumor sa atay (*benign* man o *malignant*)
- mayroong namuong dugo *(blood clot)* sa isang ugat (thrombosis) sa, halimbawa, inyong binti, baga o mata.

Mga babala at mga pag-iingat

Kausapin ang inyong doktor bago gumamit o habang kayo ay gumagamit ng Jadelle *implants*, kung ang alinman sa sumusunod na mga sintomas ay mangyayari:

- mga pananakit ng ulo na *migraine* o pagdalas ng mga pag-atake ng *migraine*
- paulit-ulit na mga pananakit ng ulo o mga problema sa paningin, lalo na kung sobra ang inyong timbang o bumigat ang timbang kamakailan lamang
- biglang mga pananakit ng ulo o pagsusuka, pagkahilo o pagkawala ng malay, mga problema sa paningin o pagsasalita, panghihina, o pamamanhid sa isang braso o binti
- pananakit sa gawing likod ng bandang ibaba *(calf)* ng binti o hindi karaniwang pamamaga ng mga braso o mga binti
- matalas na sakit sa dibdib o biglang hirap sa paghinga, o pag-ubo na may dugo
- hindi matiis na pananakit o nararamdamang pamimigat sa dibdib
- matinding pananakit ng tiyan o masakit kapag nasaling ang tiyan
- suspetsa na kayo ay maaaring buntis
- malakas na pagdurugo sa *vagina*
- ang balat o mga mata ay naninilaw
- bukol o mga bukol sa suso
- pananakit, nana o pagdurugo sa lugar na pinaglagyan ng *implants*
- mga problema sa pagtulog, panghihina, kawalan ng enerhiya, pagod o mga pagbabago ng nararamdaman
- ang *implant* ay natanggal *(expelled)*
- pag-ipon ng likido *(fluid retention)*.

Kung kayo, o isang miyembro ng pamilya ninyo, ay may ilang mga sakit, dapat ninyong talakayin sa inyong doktor kung dapat kayong magpalagay ng *implants*. Sabihin sa doktor kung kayo:

- ay nagkaroon ng isang *ectopic* na pagbubuntis (tingnan ang seksiyon ng "Pagbubuntis, pagpapasuso at kakayahang magkaanak o *fertility*")
- o ang miyembro ng pamilya ninyo ay nagkaroon ng kasaysayan ng pagkakaroon ng mga namuong dugo (thrombosis) o diperensiya ng pamumuo ng dugo *(coagulation), stroke,* atake sa puso, alta presyon, napakatataas na mga antas ng lipid o cholesterol o sakit ng ugat sa puso (tingnan ang seksiyon ng "Mga namuong dugo (thrombosis)")
- ay mayroon o nagkaroon ng mga pananakit ng ulo na *migraine* o madalas na mga pananakit ng ulo
- ay nagpapasuso
- ay mayroon o nagkaroon ng bukol o mga bukol sa suso ninyo, *mastopathy* o isang abnormal na *mammogram* (*X-ray* sa suso) o ang isang miyembro ng pamlya ninyo ay mayroon o nagkaroon ng kanser sa suso
- ay may mga problema sa apdo *(gall bladder)* ninyo, mga diperensiya sa atay o sakit sa bato
- ay may diabetes
- ay nakakaranas ng *depression*
- ay may huminang pandinig dahil sa otosclerosis
- ay may nangangati, mapulang mga pantal o maliliit na butlig (herpes gestationis) sa panahon ng pagbubuntis.

Ang inyong doktor ay maaaring magdesisyon na maaari kayong gumamit ng Jadelle *implants*, kahit na mayroon kayo ng alinman sa mga nasa itaas.

Mga namuong dugo (thrombosis)

Tulad din ng sa mga iniinom na pampigil ng pagbubuntis, nagkaroon ng mga report ng mga namuong dugo, mga atake sa puso at mga *stroke* na iniuugnay sa paggamit ng levonorgestrel *implants*.

Kung magkakaroon kayo ng namuong dugo, halimbawa, sa inyong binti, baga o mata, dapat alisin ang Jadelle *implants*.

Kung kayo ay nakaratay sa kama pagkatapos ng **operasyon**, o limitado ang pagkilos ninyo sa loob ng mahabang panahon dahil sa isang sakit o aksidente, ang panganib ng pamumuo ng dugo ay maaaring tumaas. Sa ganoong kaso, ang doktor ninyo ay maaaring magdesisyon na alisin ang Jadelle *implants*.

Presyon ng dugo

Kahit na ang mga pag-aaral ay hindi nagpakita ng malaking pagtaas ng presyon ng dugo sa mga gumagamit ng Jadelle *implants*, ang presyon ng dugo ay maaari pa ring tumaas sa ilang mga babae. Samakatwid, dapat ninyong regular na patingnan ang presyon ng dugo ninyo habang may *implants* kayo.

Kung ang presyon ng dugo ninyo ay tumataas nang hindi nagbabago habang gumagamit kayo ng Jadelle *implants*, o kung ang presyon ng dugo ninyo ay tataas nang malaki at hindi makokontrol nang sapat sa pamamagitan ng gamot sa alta presyon, ang inyong Jadelle *implants* ay dapat alisin.

Kanser sa suso

Huwag ninyong gagamitin ang *implants* kung kayo ay mayroon, o may suspetsang kayo ay mayroon, na kanser sa suso. Ang mga gumagamit ng magkakombinasyong iniinom na mga pampigil sa pagbubuntis ay natagpuang may bahagyang tumaas (1.24 beses kaysa normal) na panganib ng kanser sa suso. Ang panganib ng pagkakaroon ng kanser sa suso na na-*diagnose* sa mga gumagamit ng pampigil sa pagbubuntis na progestin lamang, tulad ng Jadelle, ay posibleng kapareho ang laki sa iniuugnay sa magkakumbinasyong iniinom na pampigil sa pagbubuntis.

Kung kayo ay may mga bukol sa suso ninyo na *benign, fibrous* (matigas) na tisyu *(tissue)* sa suso o isang abnormal na *mammogram*, o kung ang pamilya ninyo ay may kasaysayan ng kanser sa suso, dapat na maingat na subaybayan ng inyong doktor ang kundisyon ninyo.

Tumaas na presyon sa paligid ng utak *(intracranial pressure)*

Ang tumaas na presyon sa paligid ng utak ay bihirang naireport sa mga gumagamit ng levonorgestrel *implants*. Kontakin ang inyong doktor kung makakaranas kayo ng madalas, matindi o paulit-ulit na mga pananakit ng ulo o nagkakaroon kayo ng mga problema sa paningin ninyo.

Lumaking *follicles* sa *ovary* (*cysts* sa *ovary*)

Ang mga ito ay maaaring mangyari sa ilang babaeng may Jadelle *implants*. Ang ganoong *follicles* ay makikita sa isang pisikal na eksaminasyon at karaniwang kusang nawawala. Gayunman, sa mga bihirang kaso, ang mga ito ay maaaring pumilipit o pumutok, na nagiging sanhi ng pananakit ng tiyan, at maaaring mangailangan ng operasyon. Kung makakaramadam kayo ng anumang pananakit o pagkabalisa *(discomfort),* kontakin ang doktor ninyo.

Mga bata at mga kabataan *(adolescents)*

Ang kaligtasan at bisa ng Jadelle *implants* ay hindi napatutunayan sa mga babaeng ang edad ay kulang sa 18 taon.

Ibang mga gamot at Jadelle *implants*

Laging sasabihin sa inyong propesyunal na tagapangalaga ng kalusugan kung kayo ay gumagamit, gumamit kamakailan lamang o maaaring gagamit ng anumang ibang mga gamot. Gayon din, sabihin sa sinumang ibang doktor o dentista na nagrereseta ng ibang gamot (o sa *pharmacist* na kukunan ninyo ng gamot) na gumagamit kayo ng Jadelle. Masasabi nila sa inyo kung kailangan ninyong gumamit ng mga karagdagang pag-iingat sa pagpigil sa pagbubuntis (halimbawa, *condoms*) at kung ganoon, sa gaano katagal panahon (tingnan ang seksiyon ng "Ekstrang mga pag-iingat sa pagpigil sa pagbubuntis"), o kung ang paggamit ng ibang gamot na kailangan ninyo ay dapat baguhin.

Ang ilang mga gamot

ay maaaring magkaroon ng impluwensiya sa mga antas ng Jadelle sa dugo

ay maaaring maging dahilan para **mabawasan ang bisa ng Jadelle sa pagpigil sa pagbubuntis**

ay maaaring magdulot ng hindi inaasahang pagdurugo.

Kabilang dito ang:

- mga gamot na ginagamit para sa paggamot ng:
- *epilepsy* (halimbawa, primidone, phenytoin, *barbiturates*, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (halimbawa, rifampicin)
- HIV at mga impeksiyon ng *Hepatitis C Virus* (tinatawag na *protease inhibitors* at *non-nucleoside reverse transcriptase inhibitors*, halimbawa, efavirenz, nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, at tipranavir/ritonavir, nevirapine, indinavir at atazanavir/ritonavir, etravirene).
- mga impeksiyon ng *fungus* (griseofulvin, *azole antifungals*, halimbawa, itraconazole, voriconazole, fluconazole).
- alta presyon ng ugat sa pulmon (halimbawa, bosentan)
- mga impeksiyon ng bakterya (*macrolide antibiotics*, halimbawa, clarithromycin, erythromycin)
- ilang mga sakit ng puso, alta presyon (*calcium channel blockers*, halimbawa, verapamil, diltiazem)

Ang pagdurugo sa pagitan ng mga buwanang dalaw *(mid-cycle bleeding)* at hindi sinasadyang mga pagbubuntis ay naireport. Kailangan ninyong gumamit ng karagdagan, maaasahan at *non-hormonal* na mga pag-iingat sa pagpigil sa pagbubuntis tulad ng *condom* habang kayo ay gumagamit ng ibang gamot at sa loob ng **28 araw** pagkaraan. Maingat na basahin ang seksiyon ng "Ekstrang mga pag-iingat sa pagpigil sa pagbubuntis".

Kung kayo ay sumasailalim sa pangmatagalang gamutan na gamit ang mga gamot na binanggit sa itaas, ang Jadelle *implants* ay dapat na alisin at sa halip ay dapat kayong gumamit ng *non-hormonal* na pampigil sa pagbubuntis.

Kung kayo ay sumasailalim sa pangmatagalang gamutan na gamit ang mga gamot na binanggit sa itaas, dapat ninyong pag-isipan ang paggamit ng ibang paraan ng pagpigil sa pagbubuntis sa halip ng Jadelle *implants*.

o ang *herbal* na panlunas na *St. John's wort*

o *grapefruit juice*

Maaaring **maimpluwensiyahan ng Jadelle ang bisa** ng ibang mga gamot. Sang-ayon dito, ang dami ng ibang mga gamot na ito sa dugo at mga tisyu ay maaaring tumaas (halimbawa, cyclosporine, isang gamot na ginagamit para hadlangan ang di-pagtanggap *(rejection)* ng mga inilipat na bahagi ng katawan *(transplanted organs)* o bumaba (halimbawa, lamotrigine, isang gamot na ginagamit sa paggamot ng *epilepsy*).

Mga pagsusuri sa laboratoryo

Kung kailangan ninyo ng isang pagsusuri sa dugo o ibang mga pagsusuri sa laboratoryo, sabihin sa inyong doktor o sa kawani ng laboratoryo na gumagamit kayo ng Jadelle *implants* dahil ang mga ito ay maaarinng makaapekto sa mga resulta ng ilang mga pagsusuri.

Pagbubuntis, pagpapasuso at kakayahang magkaanak *(fertility)*

Pagbubuntis
Ang Jadelle *implants* ay hindi dapat gamitin sa panahon ng pagbubuntis o pinagsususpetsahang pagbubuntis.

Kung minsan, ang *ectopic* na pagbubuntis ay nangyayari sa mga gumagamit ng ibang levonorgestrel *implants*.
Kabilang sa mga sintomas ng *ectopic* na pagbubuntis ang:

- *spotting* (pagkawala ng kaunting dugo)
- pinupulikat at nananakit na tiyan

Ang mga ito ay karaniwang nagsisimula di-katagalan pagkaraan ng unang malalaktawang buwanang dalaw. Kontakin ang doktor ninyo kung may isa kayong malalaktawang buwanang dalaw o magkakaroon kayo ng pananakit ng tiyan.

Kung pagkatapos ng paglalagay ng *implants* ay nagkaroon muna kayo ng regular na buwanang dalaw at pagkaraan, ang buwanang dalaw ninyo ay mahigit sa 6 na linggong naantala, dapat ninyong tiyakin na kayo ay hindi buntis.

Kung kayo ay mabubuntis habang may nakalagay sa inyong Jadelle *implants*, dapat ninyong ipaalis ang *implants*. Walang mga pag-aaral para sa Jadelle tungkol sa epekto sa sanggol kung ginamit bago magbuntis o habang nagbubuntis. Gayunman, ang mga pildoras na pampigil ng pagbubuntis na naglalaman ng levonorgestrel na ginamit bago magbuntis o habang nagbubuntis ay hindi nagdulot ng mga nakapipinsalang epekto sa sanggol.
Kung gusto ninyong magbuntis, ang Jadelle *implants* ay maaaring alisin sa anumang oras ng inyong propesyunal na tagapangalaga ng kalusugan (tingnan ang seksiyon 3, “Kailan dapat alisin ang Jadelle *implants*?”), at pagkatapos noon, ang pagbubuntis ay maaaring maging posible na.

Pagpapasuso
Kung kayo ay nagpapasuso at gusto ninyong gamitin ang *implants* na ito, dapat ninyo itong talakayin sa doktor ninyo. Ang tigkakaunting levonorgestrel (ang *hormone* na nasa Jadelle *implants*) ay lalabas na kasama ng gatas ng suso. Ang mga pag-aaral ay hindi nagpakita ng anumang malalaking mga epekto sa paglaki o ibang pag-unlad ng mga sanggol na pinasuso na ang mga ina ay gumamit ng ibang levonorgestrel *implants* mula sa ikaanim na linggo pagkaraang manganak. Gayunman, hindi nalalaman kung ang levonorgestrel ay natatagpuan sa gatas ng suso sa unang 6 na linggo pagkaraan ng panganganak.

Kakayahang magkaanak (fertility)
Ang inyong kakayahang magkaanak *(fertility)* ay babalik pagkatapos na alisin ang *implants*.

Pagmamaneho at paggamit ng mga makina

Ang Jadelle *implants* ay walang impluwensiya sa kakayahang magmaneho o gumamit ng mga makina.

3. Paano gagamitin ang Jadelle *implants*

Ang Jadelle *implants* ay naiiba sa ibang mga paraan ng pampigil sa pagbubuntis. Ang mga ito ay dapat ilagay at alisin ng isang propesyunal na tagapangalaga ng kalusugan na nakakaalam ng proseso ng di-maselan na operasyon. Ang ilang doktor ay may mas malawak na karanasan kaysa iba sa paglalagay at pag-aalis ng *implants* na ito. Talakayin sa inyong doktor o *nurse* para malaman kung marunong siya ng paglalagay at pag-aalis ng Jadelle *implants* at kung sa palagay niya ay kabisado niya ang mga proseso.

Bago ilagay ang *implants*, gagawin muna ng inyong doktor/propesyunal na tagapangalaga ng kalusugan ang sumusunod:

- tatanungin niya kayo tungkol sa inyong medikal na kasaysayan
- magsasagawa siya ng isang pisikal na eksaminasyon
- titiyakin niya na kayo ay hindi buntis.

Paglalagay ng Jadelle *implants*

Ang Jadelle *implants* ay dapat ilagay sa loob ng pitong araw mula sa simula ng inyong buwanang pagdurugo (inyong buwanang dalaw). Sa kasong ito, hindi kayo mangangailangan ng anumang karagdagang mga pag-iingat sa pagpigil sa pagbubuntis.

Kung ang paglalagay ay ginagawa pagkaraan ng ika-7 araw (mula sa unang araw ng pagdurugo) kakailanganin ninyong gumamit ng ibang *non-hormonal* na pampigil ng pagbubuntis, halimbawa, *condom* sa loob ng hindi kukulangin sa susunod na 7 araw. Maingat na basahin ang seksiyon ng "Ekstrang mga pag-iingat sa pagpigil sa pagbubuntis".

Paglipat mula sa magkakumbinasyong *hormonal* na pampigil ng pagbubuntis (magkakumbinasyong iniinom na pampigil ng pagbubuntis /COC), *vaginal ring* o *transdermal patch*)

Ang Jadelle *implants* ay dapat na ilalagay sa araw pagkaraan ninyong inumin ang huling aktibong tableta ng inyong magkakumbinasyong iniimom na pampigil sa pagbubuntis pero pinakamatagal naman sa araw pagkaraan ng ika-7 araw ng libre-sa-tabletang patlang *(tablet-free interval)* o tabletang *placebo*.

Kung kayo ay dating gumamit ng *vaginal ring* o *transdermal patch*, ang Jadelle ay dapat ilagay sa araw ng pag-alis ng huling *ring* o *patch* ng isang *cycle pack*, pero pinakamatagal naman kapag ang ang susunod na *ring* o *patch* ay dapat nang ilagay.

Paglipat mula sa ibang progestagen-lamang na paraan (*minipill*, iniksiyon, *implant*) o mula sa isang *intrauterine system* (IUS) na nagpapakawala ng progestagen

Ang Jadelle *implants* ay maaaring ilagay

- sa anumang araw kung kayo ay naunang uminom ng *minipill*,
- sa anumang araw sa sandaling ang dating *implant* o IUS ay naalis na,
- kapag ang kasunod na iniksiyon ay gagawin na.

Paggamit ng Jadelle pagkatapos manganak, o pagkaraang makunan (miscarriage) *o magpalaglag* (abortion)

- Kung kayo ay nanganak pero hindi nagpapasuso, ang Jadelle ay maaaring ilagay agad pagkapanganak.
- Kung ang Jadelle ay ilalagay sa loob ng 3 linggo mula pagkapanganak, hindi kayo mangangailangan ng ibang mga pag-iingat sa pagpigil sa pagbubuntis.
- Kung ang Jadelle ay ilalagay nang mas matagal kaysa 3 linggo pagkatapos manganak, titiyakin ng inyong doktor na hindi kayo buntis, at dapat kayong gumamit ng ibang *non-hormonal* na mga paraan ng pagpigil sa pagbubuntis sa loob ng hindi kukulangin sa 7 araw pagkaraan ng paglalagay.
- Kung kayo ay katatapos pa lamang makunan o magpalaglag, ang *implants* ay maaaring ilagay agad. May karagdagang sasabihin sa inyo ang inyong doktor tungkol dito.

Paraan

1. Ilalagay ng doktor/propesyunal na tagapangalaga ng kalusugan ang dalawang maninipis na Jadelle *implants* sa ilalim lamang ng balat sa loob ng bandang itaas ng braso ninyo. Kung kayo ay hindi kaliwete, karaniwang sa kaliwang braso ninyo ilalagay, at kung kaliwete kayo, sa inyong kanang braso ilalagay.

2. Isang maliit na hiwa ang gagawin para maipasok ang *implants*, para gawin ito, isang lokal na *anaesthetic* ang gagamitin sa lugar na paglalagyan.

3. Ang *implants* ay ilalagay sa ilalim ng balat, nang isa-isa. sa pamamagitan ng isang hiwalay na instrumento (trocar). Dahil ang lugar na paglalagyan ay ginamitan ng *anaesthetic*, dapat na hindi kayo makakaramdam ng anumang pananakit.

4. Pagkatapos ng proseso, ang lugar na pinaglagyan ay isasara sa pamamagitan ng tape na para sa balat at lalagyan ng benda. Panatilihing tuyo at may benda ang sugat sa loob ng 3 araw. Huwag hahayaang magkaroon ng pasa ang lugar na pinaglagyan sa panahong ito at huwag ibubuhat ng anumang bagay na mabigat ang brasong iyon.

Maaaring magkaroon ng kaunting pagbabago ng kulay, pagpapasa at pamamaga sa lugar na nilagyan ng *implant* sa loob ng ilang araw pagkaraan ng paglalagay, pero ang mga ito ay hindi dapat makasagabal sa inyong mga normal na gawain. Paminsan-minsan, maaaring may mangyaring impeksiyon o maaaring magkaroon ng panandaliang pananakit, pagkabalisa *(discomfort)* o pangangati.

Ang sumusunod na mga reaksiyon ng balat ay naireport na iniuugnay sa paglalagay ng ibang kaparehong levonorgestrel *implants:*

- pagkakaroon ng pilat, pagpapaltos, pagtatalop ng balat, pagsusugat *(ulceration)*, pangingilig *(tingling)* at pamamanhid.

Makipag-usap sa inyong doktor kung kayo ay nag-aalala – tingnan din ang seksiyon 4.

Pagkatanggal at pagbabago ng posisyon ng *implant*

Posible na ang isang *implant* ay matanggal bago gumaling ang hiwa sa inyong braso, lalo na kung ang *implants* ay ipinasok nang napakalapit sa ibabaw ng balat o napakalapit sa hiwa o kung ang lugar na nilagyan ng *implant* ay nagkaroon ng impeksiyon Kung mangyayari ito, kontakin ang inyong doktor dahil ang natanggal na *implant* ay dapat na laging papalitan ng isang bago at *sterile* na *implant*.

Kailangan din ninyong gumamit ng karagdagang maaasahang *non-hormonal* na mga pag-iingat sa pagpigil sa pagbubuntis tulad ng mga *condom*, hanggang magawa ninyong makipagkita sa doktor ninyo. Maingat na basahin ang seksiyon ng "Ekstrang mga pag-iingat sa pagpigil sa pagbubuntis".

Maaaring gumalaw ang posisyon ng *implant* sa braso ninyo. Ito ay hindi madalas na naireport, gayunman, maaari kayong makaramdam ng pananakit o pagkabalisa *(discomfort)*. Kung nararamdaman ninyo na gumalaw ang *implant*, kontakin ang doktor ninyo.

Ekstrang mga pag-iingat sa pagpigil sa pagbubuntis

Kung kailangan ninyo ng ekstrang mga pag-iingat sa pagpigil sa pagbubuntis

- gumamit ng maaasahang *non-hormonal* na pampigil ng pabubuntis, tulad ng mga *condom*, o
- huwag makipagtalik.

Huwag gumamit ng paraang batay sa rhythm o temperatura bilang karagdagang mga pag-iingat sa pagpigil sa pagbubuntis. Ang mga pagbabago sa temperatura ng katawan at *mucus* sa *cervix* na normal na nangyayari sa panahon ng buwanang dalaw ay maaaring hindi mangyari kapag gumagamit ng Jadelle *implants*.

Kailan kayo dapat makipagkita sa inyong propesyunal na tagapangalaga ng kalusugan

Pagkalipas ng ilang panahon mula sa paglalagay ng *implants*, maaaring gustuhin ng inyong doktor/propesyunal na tagapangalaga ng kalusugan na suriin ang lugar na pinaglagyan ng *implant.*

Tulad ng sa ibang *hormonal* na pampigil ng pagbubuntis, kakailanganin ninyo ng regular na mga *check-up* habang kayo ay gumagamit ng Jadelle *implants*. Sasabihin sa inyo ng inyong doktor kung gaano kadalas magpapa-*check-up*.

Kailan dapat alisin ang Jadelle *implants?*

Maaari kayong magdesisyong ipaalis ang inyong Jadelle *implants* sa anumang oras, at pagkatapos noon, ang pagbubuntis ay posible nang mangyari. Samakatwid, kung ayaw ninyong lagyan kayo isa pang *set* ng Jadelle *implants* at ayaw ninyong mabuntis, dapat kayong magsimulang gumamit agad ng ibang paraan ng pagpigil sa pagbubuntis.

Ang Jadelle *implants* ay **dapat alisin sa katapusan ng 5 taon**. Huwag ipagpapaliban ang pag-alis nito pagkaraang lumipas ang 5 taon, dahil magsisimulang mawala ang bisa ng *implants* pagkaraan ng panahong iyon. Kung hindi kayo makapupunta sa isang doktor para alisin ang mga ito sa katapusan ng ikalimang taon, dapat kayong gumamit ng mga karagdagang pag-iingat sa pagpigil sa pagbubutis at ipaalis ang *implants* sa pinakamaagang panahon. Maingat na basahin ang seksiyon ng "Ekstrang mga pag-iingat sa pagpigil ng pagbubuntis".

Kung gusto ninyong patuloy na gamitin ang *implants*, maaaring maglagay ng isang bagong *set* kapag ang nakalagay na *implants* ay inalis.

Kung kayo ay tumitimbang nang mahigit sa 60 kilo, maaaring irekomenda ng inyong doktor na ang *implants* ay alisin at palitan pagkaraan ng 4 na taon kaysa maghintay sa ika-5 taon.

Paraan ng pag-alis ng Jadelle *implants*

Ang pag-alis ng Jadelle *implants* ay maaaring maging mas mahirap kaysa paglalagay sa mga ito. Ito ay maaaring maging mas matagal at maging mas masakit. Maaari itong mag-iwan ng mga pilat (scars) – isang panganib na wala sa karamihan ng ibang mga paraan ng pagpigil sa pagbubuntis.

1. Dahil ang *implants* ay nasa ilalim ng balat sa loob ng bandang itaas ng inyong braso, ang mga ito ay dapat alisin ng isang doktor. Huwag ninyong susubukang kayo ang mag-alis ng mga ito.
2. Ang lugar ng *implant* ay lalagyan ng *anaesthetic* at gagawa ng maliit na hiwa sa balat.
3. Pagkaalis ng *implants*, panatilihin ang sugat na malinis, tuyo at may benda sa loob ng 3 hanggang 5 araw o hanggang ang balat ay maghilom.

Maaaring magkaroon ng pagpapasa sa lugar kasunod ng pag-alis sa *implants*. Kung ang *implants* ay inilagay nang napakalalim, maaaring ang mga ito ay mas mahirap alisin.

Kung ang dalawang *implants* ay hindi maaalis sa unang pagtatangka, kakailanganin ninyong pumunta uli sa doktor para sa isang bagong pagtatangka. Dapat kayong gumamit ng ibang paraan ng pagpigil sa pagbubuntis hanggang ang *implants* ay parehong maalis.

Sa mga kaso kung saan ang pag-aalis ng *implants* ay naging mahirap, nagkaroon ng mga report ng pananakit, pamamanhid, pangingilig *(tingling)* at pagkakaroon ng pilat sa bandang itaas ng braso.

4. Posibleng *side effects*

Tulad ng lahat ng gamot, ang gamot na ito ay maaaring magdulot ng *side effects*, bagamat hindi lahat ng tao ay nagkakaroon ng mga ito.

Ang pinakamadalas na naireport na *side effect* ay:

- hindi regular na pagdurugo ng buwanang dalaw, kung saan ang mga buwanang dalaw ay maaaring tumagal (tumatagal nang mas maraming araw kaysa karaniwan), mas mahina o mas malakas, mas madalas o mas madalang, o maaaring magkaroon ng *spotting* sa pagitan ng mga buwanang dalaw. Sa ilang babae, ang mga buwanang dalaw ay maaaring tuluyan nang huminto.

Ang ganoong hindi regular na pagdurugo ay nangyayari sa karamihan ng mga gumagamit sa unang taon at madalas na nababawasan habang patuloy na ginagamit ang Jadelle *implants*. Sa kabila ng mas maraming araw ng pagdurugo, ang nawawalang dugo sa bawat buwan ay karaniwang hindi sumusobra sa nawawala mula sa normal na buwanang dalaw.

Ang mga antas ng asukal at taba (lipid) sa dugo ay maaari ring magbago sa panahon ng paggamit sa *implants* na ito. Samakatwid, ang mga pasyenteng may diabetes or diperensiya sa lipid *metabolism* ay dapat na masusing susubaybayan sa panahon ng paggamit ng *implants* na ito. Ang mga antas ng bilirubin sa dugo na naglalarawan sa paggana ng atay ay maaaring tumaas sa simula ng paggamit ng *implants* na ito.

Kung kayo ay nagsusuot ng ***contact lenses**,* maaaring makaranas kayo ng mga pagbabago sa paningin o maaaring hindi na ninyo maisuot ang *contact lenses* ninyo. Kung mangyayari ito, dapat ninyong kontakin ang ang doktor ninyo.

Ang sumusunod na *side effects* ay naireport sa mga klinikal na pag-aaral:

Napakakaraniwang *side effects:* maaaring makaapekto sa mahigit sa 1 sa 10 babae
- pananakit ng ulo, pagiging nerbiyoso, pagkahilo
- pakiramdam na may sakit (naduduwal)
- pamamaga o inflammation ng *cervix, vaginal discharge,* pangangati ng labas ng ari, pananakit ng bandang ibaba ng tiyan, pananakit ng suso
- pagbigat ng timbang

Karaniwang *side effects:*** maaaring makaapekto sa hanggang 1 sa 10 babae
- mga pagbabago ng nararamdaman, *depression*, huminang kagustuhang makipagtalik, pananakit habang nakikipagtalik
- *migraine*
- pagsikdo *(palpitation)*, pananakit ng dibdib
- alta presyon, *varicose veins*
- hirap sa paghinga
- pagkabalisa *(discomfort)* sa tiyan
- ang bilirubin, na ginagawa ng atay ninyo, ay maaaring tumaas (makikita ito sa mga pagsusuri sa dugo)
- tagihawat, iritasyon ng balat *(contact dermatitis)*, pagkalugas ng buhok, sobrang pagdami ng buhok, singaw sa balat, pangangati, pagbabago ng kulay ng balat
- mga sintomas ng daanan ng ihi *(urinary tract)*
- pamamaga o inflammation ng *vagina,* mga *cysts* sa *ovary,* mga bukol sa suso na *benign,* tumatagas na likido sa suso *(breast discharge)*
- pananakit o pangangati sa lugar na nilagyan ng *implant*, pananakit sa pangkalahatan, pagod, pananakit ng likod
- pagbaba ng timbang

Hindi karaniwang *side effects:*** maaaring makaapekto sa hanggang 1 sa 100 tao
- pagpapasa o impeksiyon sa lugar na nilagyan ng *implant*

Bihirang *side effects:*** maaaring makaapekto sa hanggang 1 sa 1,000 tao
- pagkatanggal (expulsion) ng *implant* (tingnan ang seksiyon 3 “Pagkatanggal at pagbabago ng posisyon ng *implant*”), pananakit ng braso, pamamanhid, pangingilig *(tingling)* at pagkakaroon ng pilat, hirap sa pag-alis ng *implants*, pinsala ng nerve sa braso na kaugnay ng pag-alis ng *implant*, pangingitim ng balat sa ibabaw ng lugar na nilagyan ng *implant*

Sa mga bihirang okasyon, ang mga *ectopic* na pagbubuntis ay naireport (tingnan ang seksiyon 2 “Pagbubuntis, pagpapasuso at kakayahang magkaanak *[fertility]*”).

Ang pangingitim ng balat *(hyperpigmentation)* ay nangyari sa mga gumagamit ng ibang levonorgestrel *implants*.

Kung magkakaroon kayo ng anumang *side effects,* kausapin ang inyong doktor, *pharmacist* o *nurse*. Kabilang dito ang anumang posibleng *side effects* na hindi nakalista sa *leaflet* na ito.

Pagrereport ng *side effects*

Kung magkakaroon kayo ng anumang *side effects*, kausapin ang inyong doktor, *pharmacist* o *nurse*. Kabilang dito ang anumang posibleng *side effects* na hindi nakalista sa *leaflet* na ito. Sa pamamagitan ng

pagrereport ng *side effects*, maaari kayong makatulong na magbigay ng karagdagang impormasyon sa kaligtasan ng gamot na ito.

5. Paano itatago ang Jadelle *implants*

Huwag itatago nang mas mainit sa 30°C.

Itago ang gamot na ito sa hindi nakikita at naaabot ng mga bata.

Ang Jadelle *implants* ay hindi dapat gamitin paglampas sa petsa ng pagkapaso (expiry date) na nakaimprenta sa pakete. Ang petsa ng pagkapaso ay tumutukoy sa huling araw ng buwang iyon.

6. Mga nilalaman ng pakete at ibang impormasyon

Ano ang nilalaman ng Jadelle *implants*

Ang produkto ay binubuo ng dalawang *implants* na ipapasok sa ilalim ng balat (subdermally).
Ang **aktibong sangkap** ay levonorgestrel. Ang bawat *implant* ay naglalaman ng 75 mg levonorgestrel.
Ang **ibang mga sangkap** ay: polydimethylsiloxane, anhydrous colloidal silica.

Ano ang itsura ng Jadelle *implants* at mga nilalaman ng pakete

Ang *set* ay naglalaman ng dalawang nababaluktot *(flexible)*, selyado, puti o *off-white* na parang maliliit na baras *(rod-like)* na *implants*, mga 43 mm ang haba at 2.5 mm ang *diameter*.
Ang dalawang *sterile* na *implants* ay nakasilid sa isang bag na gawa sa espesyal na plastik/hinabi *(specialist plastic/woven)* na materyales. Ang paketeng ito ay para sa isang paggamit *(single use)* lamang.

Ginagawa ng

Bayer Oy
Pansiontie 47, Turku, 20210, Finland

Inaangkat ng:
Bayer Philippines, Inc.
8th Floor, Science Hub, Tower 1
Campus Avenue Corner Turin Street
McKinley Hill Cyberpark
Pinagsama, Taguig City, Metro Manila

Kung gusto ninyong magreport ng isang reklamo sa produkto o *side effect,* mangyaring kontakin ang inyong propesyunal na tagapangalaga ng kalusugan o ang Philippine FDA sa adr@fda.gov.ph
Ang mga katanungan ay maaari ring ipadala sa:
Bayer Philippines, Inc.
Taguig City, Philippines
E-mail: medinfoph@bayer.com drugsafety.philippines@bayer.com

Pag-iingat: Ang Foods, Drugs, Devices and Cosmetics Act ay nagbabawal sa pamamahagi nang walang reseta.

Ang leaflet na ito ay huling binago noong Enero 2016.
DR-XY48818
Date of First Authorization: 21 July 2023

Card* ng Paalala sa Pasyente para sa Jadelle *sine inserter* 2 x 75 mg *implants
Panahon ng paggamit: 5 taon

Batch No.

Ang *implants* ay inilagay ni:

_____

Numero ng telepono ng doktor o *nurse*:

_____

Petsa:

_____

Susunod na pagbisita: Mga komentaryo:

_____

_____

_____

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