

1.Name of the Product

**Xylometazoline Hydrochloride +
Lysozyme Hydrochloride**

**RINOBACT P® SPRAY
0.5 mg/0.5 mg per mL
Nasal Spray Solution
Decongestant**

2.Description of the Product

Nasal spray, solution
RINOBACT P SPRAY is a clear and colourless solution.
RINOBACT P SPRAY is packed in 10-ml amber glass bottles, with pump + applicator, and a protective cap.
A single actuation (pressing the pump) will release 0.07 ml of the solution containing 0.035 mg of xylometazoline hydrochloride and 0.035 mg of lysozyme hydrochloride.

3.What is in the Medicine?

1 ml of nasal spray, solution contains:

xylometazoline hydrochloride 0.5 mg
lysozyme hydrochloride 0.5 mg
(corresponding to 20 000 FIP U)

RINOBACT P SPRAY contains the following excipients: propylene glycol, sodium chloride, methyl parahydroxybenzoate (E218), disodium edetate, propyl parahydroxybenzoate (E216), sodium hydroxide and purified water.

4.Strength of the Medicine

0.5 mg/ 0.5 mg per mL

5.What is this Medicine used for?

RINOBACT P SPRAY contains two active substances xylometazoline and lysozyme.
Xylometazoline works by narrowing the blood vessels (vasoconstricting effect) and thusly reduces swelling of the nasal mucosa (decongestant effect).

Lysozyme is a natural component present in bodily secretions such as mucus, tears, and saliva. Lysozyme has the properties of moisturizing and protecting the nasal mucosa. In addition, it acts in the nasal cavity to accelerate the ciliary beats and stimulate the activity of the nasal cilia, which helps in the elimination of accumulated secretion, allergens and infectious components of the nose.
With its action, lysozyme contributes to the efficacy of xylometazoline.

RINOBACT P SPRAY is used:

- For reduction of the nasal mucosal swelling and protection of nasal mucosa in common cold (viral rhinitis);
- For reduction of the nasal mucosal swelling and irritation of the nasal mucosa associated with vasomotor rhinitis (nasal secretion discharge due to occasional blood vessel dilation) and allergic rhinitis;
- For alleviating nasal secretion discharge in paranasal sinuses inflammation, as well as in catarrhal inflammation of the middle ear associated with cold.

RINOBACT P SPRAY is intended for use in children aged between 2 and 12 years.

6.How much and how often should you use this Medicine?

Dosage

Unless otherwise prescribed by your doctor, the usual dose is:
• Single spraying (press the pump once) into each nostril, 2 to 3 times daily.

RINOBACT P SPRAY must not be used more than 3 times a day.

Doses higher than recommended ones must not be used.

Method of use

RINOBACT P SPRAY is intended for nasal usage (for nose).

- Blow your nose thoroughly before every use of RINOBACT P SPRAY.
- Remove the protective cap before use (Figure 1).



- Before the first usage, press the spray pump several times until a consistent spray emerges. The spray is then ready for further usage.
- Hold the bottle upright. Insert the tip of the actuator into the nostril, and press the pump once shortly and strongly (Figure 2).



- Breathe gently through the nose at the moment of spraying. Repeat the same procedure in the other nostril as well.
- After the application, it is recommended to wipe the actuator and pump with a clean paper tissue, and replace the protective cap.
- The last daily application should favourably occur before bedtime.

For hygienic reasons and to avoid infections, it is advised that the same spray bottle must always be used by only one patient.

Duration of treatment

- RINOBACT P SPRAY should not be applied for longer than 7 days, unless the doctor prescribed otherwise. If your symptoms get worse or if there is no relief after 7 days, contact your doctor right away.
- The medicine can be applied again only after a lapse of several days.
- In treatment of chronic rhinitis, RINOBACT P SPRAY may be used only under the doctor's supervision due to the risk of the nasal mucosa's atrophy (thinning and damage).
- If you have an impression that the effect of RINOBACT P SPRAY is too strong or too weak, please talk to your doctor or pharmacist.

7.When should you not take this Medicine?

- If you are hypersensitive (allergic) to xylometazoline or lysozyme or any other ingredient of this medicine (listed in section 6).
- If you are hypersensitive to egg white
- If you have dry inflammation of nasal mucosa (*rhinitis sicca*).
- If you were recently subjected to surgical removal of hypophysis through the nasal cavity (transsphenoidal hypophysectomy) or another surgery during which meninges were exposed.
- In new-borns, infants and toddlers aged up to 2 years.

8.Care that should be taken when taking this Medicine?

Consult your doctor before you use RINOBACT P SPRAY:

- If you have raised eye pressure (glaucoma), especially in case of narrow-angle glaucoma;
- If you have severe heart and blood vessels disease (e.g. coronary heart disease, hypertension);
- If you have heart disease (e.g. long QT syndrome);
- If you are taking medicines to treat depression from the group of monoamine oxidase inhibitors (MAO inhibitors) or other medicines that can increase your blood pressure;
- If you have adrenal gland tumour (pheochromocytoma);
- If you have metabolism disorder, such as hyperthyroidism (thyroid gland overactivity) or diabetes;
- If you suffer from prostatic hyperplasia (enlargement);
- If you suffer from porphyria (metabolic disorder affecting the skin and/or central nervous system).

In such cases, after estimating possible benefits and risks, your doctor will determine whether you should use RINOBACT P SPRAY.

Due to the risk of atrophy (thinning and damage) of the nasal mucosa, the use of this medicine in patients with chronic inflammation of the nasal mucosa should be under the supervision of a physician.

Use in children

RINOBACT P SPRAY is not intended for use in new-borns, infants and toddlers aged up to 2 years.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

As a precautionary measure, it is not recommended to use this medicine during pregnancy.

Lactation

It is not recommended to use this medicine in the period of breast-feeding.

Driving and using machines

If RINOACT P SPRAY is used as directed, reduced ability to drive and use machines is not expected.

Important information about some of the ingredients of RINOACT P SPRAY

- RINOACT P SPRAY contains propylene glycol which may irritate the skin when used locally.
- RINOACT P SPRAY contains methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216). Both of these ingredients may cause allergic reactions (possible delayed hypersensitivity reactions), exceptionally bronchospasm.

9.Undesirable Effects of this Medicine

Like all medicines, RINOACT P SPRAY can cause side effects, although not everybody gets them.

Side effects are listed by organic systems and frequency categories.

The frequency of side effects is listed below:

- Very common (in more than 1 in 10 treated patients);
- Common (in 1 to 10 in 100 treated patients);
- Uncommon (in 1 to 10 in 1,000 treated patients);
- Rare (in 1 to 10 in 10,000 treated patients);
- Very rare (in less than 1 in 10,000 treated patients);
- Unknown (frequency cannot be estimated from the available data).

Nervous system disorders

Very rare: restlessness, insomnia, fatigue (drowsiness, excessive calmness – sedation), headache, hallucinations (mainly in children).

Heart disorders

Rare: heart palpitations, fast heartbeat, hypertension.
Very rare: heart arrhythmias (an irregular heartbeat).

Respiratory system disorders

Common: burning or pricking sensation in the nasal mucosa, dry nasal mucosa, sneezing.
Uncommon: increased nasal mucosa swelling after fading, nasal bleeding.
Very rare: apnoea (cessation of breathing) in younger infants and new-borns.

Disorders of musculoskeletal and binding tissue

Very rare: seizures (convulsions), particularly in children.

Immune system disorders

Uncommon: hypersensitivity reactions (rash, itching, swelling of the skin and mucosa).
Rare: severe allergic reaction (anaphylactic shock), sudden swelling of the face and neck (Quincke's oedema).

10.What other medicine or food should be avoided while taking this Medicine?

Concurrent use of RINOACT P SPRAY and the following medicines may result in an increase in blood pressure:

- Tricyclic antidepressants;
- Antidepressants from monoamine oxidase inhibitors group, such as tranylcypromine;
- Medications that can elevate blood pressure.
- Whenever possible, concomitant usage of RINOACT P SPRAY and the above-listed medicines should be avoided.

Using food and drinks with RINOACT P SPRAY

No special remarks.

11.What should you do if you miss a dose?

If you forget to use the medicine, apply it as soon as you remember, and then continue the therapy at your regular scheme. Keep in your mind that you must not use more than three doses of this medicine within 24 hours. Never use a double dose to make up for the forgotten dose.

12.Signs and Symptoms of Overdose

Poisoning with xylometazoline can have confusing symptoms due to alternative appearance of phases of stimulation and phases of suppression of the central nervous system and cardiovascular system. Stimulation of the central nervous system is manifested in symptoms such as anxiety, agitation, hallucinations and convulsions (cramps). Symptoms of the inhibition of central nervous system are lowered body temperature, lethargy, sleepiness and coma.

In addition, the following symptoms may also occur: narrowing or widening of the pupils, fever, sweating, paleness, bluish discoloration of the skin and lips (cyanosis), heart palpitations, breathing disorders and temporary cessation of breathing (apnoea), nausea and vomiting, psychological disorders, increase or decrease in blood pressure, heart arrhythmia, too fast or too slow heartbeat.

In overdose cases in children, symptoms of the central nervous system like seizures and coma are frequent, but the following also appear: slowed heartbeat, apnoea (cessation of breathing), and hypertension which can be in alternation with hypotension.

13.What to do when you have taken more than the recommended dose?

In case of taking more than the recommended dose, contact your doctor or the nearest hospital straight away, because you will need appropriate therapy and monitoring. Bring this medicine or patient information leaflet with you.

14.How should you keep this Medicine?

Store at temperatures not exceeding 30°C. Do not freeze.
Use within 90 days after the first opening.
Keep out of reach and sight of children.
Do not use this medicine after the expiry date which is stated on the label.

15.When should you consult your doctor?

If your symptoms get worse or if there is no relief after 7 days, contact your doctor right away.

16.Imported and Distributed by:

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17.Manufactured by:

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Bosnia and Herzegovina

18.ADR Reporting Statement

For suspected adverse drug reaction, report to the FDA:
www.fda.gov.ph.

Patients should seek medical attention immediately at the first sign of any adverse drug reaction.

19.Registration Number: DRP-12883

20.Date of First Authorization: 25 October 2022

21.Date of Revision of Patient Information Leaflet: N/A