GRIFOLS

Igantet® 250 and 500 I.U.

HUMAN ANTITETANUS IMMUNOGLOBULIN
Solution for injection in pre-filled syringe

Composition

	250 I.U.	500 I.U.
- Active ingredient:		
Human antitetanus immunoglobulin	250 I.U.	500 I.U.
(Human protein	160 mg	320 mg)
(Human immunoglobulin percentage	≥ 95% Ig	≥ 95% Ig)
- Excipients:		
Glycine, Sodium chloride		
Water for injection q.s.	1 ml	2 ml

Pharmaceutical form and content

Solution for injection in pre-filled syringe containing 250 or 500 I.U. of human antitetanus immunoglobulin.

Activity

Igantet® is a solution for injection of human antitetanus immunoglobulin that contains antibodies to tetanus toxin and that has been subjected to a pasteurisation process. It is prepared from pooled donors' plasma containing specific antibodies against the toxin of Clostridium tetani.

Holder of the marketing authorisation

Instituto Grifols, S.A.
Can Guasch, 2 - Parets del Vallès
08150 Barcelona - SPAIN

Therapeutic indications

- Prophylaxis in persons with recent injuries that might be contaminated with tetanus spores and who did not receive vaccination in the previous 10 years or whose prior vaccination regimen was incomplete or is unknown.
- Treatment of clinically manifest tetanus.

Contraindications

The lethal risk associated with tetanus rules out any potential contraindication (see item corresponding to Precautions).

Precautions

Do not give this product intravascularly (risk of shock). Injections have to be made intramuscularly, and care should be taken to draw back the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

True allergic responses to human antitetanus immunoglobulin given in the prescribed intramuscular manner are rare. In the case of shock, treatment should follow the guidelines of shock therapy.

Intolerance to immunoglobulins is likely to develop in the very rare cases of IgA deficiency, when the patient has antibodies against IgA.

Patients should be observed for at least 20 minutes after administration.

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to transmission of infective agents cannot be totally excluded. This also applies to pathogens of unknown nature. The risk of transmission of infective agents is however reduced by:

- selection of donors by a medical interview and screening of individual donations and plasma pools for HBsAg and antibodies to HIV and HCV.
- testing of plasma pools for HCV genomic material.
- inactivation/removal procedures included in the production process that have been validated using model viruses. These procedures are considered effective for HIV, HCV, HAV and HBV.

The viral inactivation/removal procedures may be of limited value against non-enveloped viruses such as parvovirus B19 and other transmissible infectious agents.

Interactions and incompatibilities

Live attenuated virus vaccines

Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella.

Interference with serological testing

After injection of immunoglobulin the transitory rise of the various passively transferred antibodies in the patients' blood may result in misleading positive results in serological testing.

Incompatibilities

Igantet® must not be mixed with any other drugs.

Warnings

Pregnancy and lactation

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and, therefore, should only be given with caution to pregnant women or breast-feeding mothers. Long lasting clinical experience with immunoglobulin, in particular the application of anti-D immunoglobulin, does indicate that no harmful effects on the course of pregnancy, on the foetus and the neonate are to be expected.

Immunoglobulins are excreted into the mother's milk and may contribute to the transfer of protective antibodies to the neonate.

Effects on ability to drive

There are no indications that human antitetanus immunoglobulin may impair the ability to drive and use machines.

Posology

Slow injection by the i.m. route.

In case of clotting disorders where intramuscular injections are contraindicated, human antitetanus immunoglobulin can be administered subcutaneously. Careful manual pressure with a compress should be applied therefore on the site after injection.

If large total doses (≥ 5 ml) are required, it is advisable to administer them in divided doses at different sites.

Antitetanus immunoglobulin and vaccine should be administered using different syringes, needles and injection sites.

Besides wound cleansing or debridement and intramuscular human antitetanus immunoglobulin injection, active immunisation with the tetanus vaccine must be started simultaneously in a separate site of the body according to the following instructions:

- Clean-minor wounds

  It is not recommended to administer neither a revaccination nor antitetanus immunoglobulin to patients who did receive the last booster dose in the previous 10 years and whose prior antitetanus vaccination regimen was complete.

  It is recommended to administer a vaccine dose to patients who did not receive the last booster dose in the previous 10 years and whose prior antitetanus vaccination regimen was incomplete or is unknown. Antitetanus immunoglobulin administration is not necessary.

- Dirty-major wounds

  It is not necessary to administer a revaccination to patients who did receive the last booster dose in the previous 5 years and whose prior antitetanus vaccination regimen was complete. However, if more than 5 years have passed since the last booster dose, a vaccine dose should be administered to the patient. In both cases, it is not necessary to administer antitetanus immunoglobulin.

  It is necessary to administer a vaccine dose together with antitetanus immunoglobulin to patients whose prior antitetanus vaccination regimen was incomplete or is unknown.

The antitetanus vaccine to be used may contain only tetanus toxoid or tetanus toxoid together with diphtheric toxoid (adults dT vaccine). The latter must not be administered to wounded immunodeficient patients.

It is recommended that the physician determines if a minor wound is “tetanus prone”, based on the likelihood that Clostridium tetani was present on the object which caused the wound.

Children and adults have to receive the same dose.

- Prophylaxis of tetanus

  250 I.U. by intramuscular route.

  This dosage should be doubled (i.e. 500 I.U.) in case of anfractuous (dirty deep wounds with tissue destruction) or infected wounds or if the injury has occurred more than 24 hours before, or in adults weighing more than the average.

- Therapy of clinically manifest tetanus

  Several studies suggest the value of human antitetanus immunoglobulin in the treatment of clinically manifest tetanus using single doses of 3000 to 6000 I.U. i.m. in combination with other appropriate clinical procedures.

Instructions fo use

Dissolved products should be visually inspected for particulate matter and discoloration prior to administration.

Do not use solutions which are cloudy or have deposits.

The product should be warmed to room temperature or body temperature before use.

Overdose

Consequences of overdosage are not known.

Undesirable effects

Local pain and tenderness can be observed at the injection site; this can be prevented by dividing larger doses over several injection sites.

Occasionally fever, cutaneous reactions and chills occur. In rare cases: nausea, vomiting, hypotension, tachycardia and allergic or anaphylactic type reactions, including shock, are reported.

For information on viral safety see Precautions.

If any adverse reaction not enclosed in this item appears, inform your physician or pharmacist.

Storage

Store between 2 - 8 ºC.

Shelf-life

Do not use after the expiry date given on the label.

Sizes

- Igantet® 250 I.U.
- Igantet® 500 I.U.

Keep out of the reach and sight of children

Revision of the text

May 2005

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