GRIFOLS

# Igantibe® 200 IU/ml

## HUMAN ANTIHEPATITIS B IMMUNOGLOBULIN
Solution for injection

**Composition**

| | 100 IU/0.5 ml | 600 IU/3 ml | 1000 IU/5 ml |
|---|---|---|---|
| - Active ingredient: | | | |
| Human antihepatitis B immunoglobulin | 100 IU | 600 IU | 1000 IU |
| (Human protein | 80 mg | 480 mg | 800 mg) |
| (Human immunoglobulin percentage | ≥ 95% IgG | ≥ 95% IgG | ≥ 95% IgG) |
| - Excipients: | | | |
| Glycine, Sodium chloride | | | |
| Water for injection q.s. | 0.5 ml | 3 ml | 5 ml |

**Pharmaceutical form and content**

Solution for injection containing 100 IU, 600 IU or 1000 IU of human antihepatitis B immunoglobulin.

**Activity**

Igantibe® is a solution for injection of human antihepatitis B immunoglobulin that contains specific antibodies (mainly IgG) against the hepatitis B virus and that has been subjected to a pasteurisation process.

**Manufacturer**

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**Therapeutic indications**

Igantibe® 100 IU/0.5 ml, 600 IU/3 ml and 1000 IU/5 ml:

- Post-exposure prophylaxis in persons who did not receive prior vaccination, or whose prior vaccination regime is incomplete or when the antibody level is inadequate (i.e. < 10 mIU/ml). This passive immunisation in persons at increased risk of infection should be concomitant with vaccination. This post-exposure prophylaxis should be considered following either parenteral exposure, direct mucous membrane contact, oral ingestion, sexual exposure to an HBsAg positive person, and for infants < 12 months of age if the mother or the primary contact person has acute hepatitis B virus infection.

Igantibe® 100 IU/0.5 ml and 600 IU/3 ml:

- Prophylaxis for infants born to HBsAg positive mothers. Infants should receive human antihepatitis B immunoglobulin and the first dose of hepatitis B vaccine at the same time.

**Contraindications**

Intolerance to homologous immunoglobulins.

Allergic response related to any of the components.

The human antihepatitis B immunoglobulin should not be administered to patients suffering from severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.

**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 antihepatitis B 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.

Suspicion on allergic or anaphylactic type reactions requires immediate discontinuation of the injection.

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

Igantibe® 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 if clearly indicated to pregnant women and 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.

Effects on ability to drive

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

**Posology**

Slow injection by the i.m. route.

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

- Post-exposure prophylaxis:

  After exposure to material containing or with a high risk of containing HBs-antigen in a non-vaccinated person, the usual practice is to inject 12 IU to 20 IU per kg of body weight as soon as possible, preferably within 24 hours and initiate hepatitis B vaccination.

  After exposure in a vaccinated person who is known not to have responded to the primary vaccine series, give either a single dose (12 - 20 IU/kg) of human antihepatitis B immunoglobulin and a dose of hepatitis B vaccine as soon as possible or two doses of human antihepatitis B immunoglobulin (one given in the first 24 hours and the second 1 month later).

  If the exposed person has already been vaccinated and the response is unknown, test for anti-HBs antibodies. If the response is inadequate (< 10 mIU/ml) give one dose of human antihepatitis B immunoglobulin immediately and a booster of vaccine. If the response is adequate, there is no necessity of treatment.

  If facilities are not available for testing, immediately give one dose of human antihepatitis B immunoglobulin.

- Prophylaxis in neonates of HBsAg positive mother:

  40 IU/kg body weight within 12 hours of birth and the first dose of hepatitis B vaccine.

The administration of hepatitis B vaccine should be at a different site of the body with separate lymphatic drainage.

HBsAg positive persons should not be given antihepatitis B immunoglobulin as no prophylactic effect will be expected.

**Instructions for 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.

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to transmission of infective agents cannot be totally excluded (see item corresponding to Precautions).

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

**Storage**

Store between 2 - 8 °C.

**Shelf-life**

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

**Sizes**

- Igantibe® 200 IU/ml, 100 IU/0.5 ml
- Igantibe® 200 IU/ml, 600 IU/3 ml
- Igantibe® 200 IU/ml, 1000 IU/5 ml

Keep out of the reach and sight of children

**Revision of the text**