Package leaflet: information for the patient

GAMMA anty-HBs 200, 200 IU/ml

Solution for injection

Human hepatitis B immunoglobulin

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GAMMA anty-HBs 200 is and what it is used for

GAMMA anty-HBs is a solution for intramuscular injections containing 200 IU of anti-HBs antibodies in aqueous solution.

The medicine used as a preventive measure protects the body against hepatitis B virus (HBV) infection. Anti-HBs immunoglobulins administered intramuscularly in case of infection bind HBs antigen and prevent hepatitis B virus infection (HBV). Passive immunity lasts for approximately 3 to 4 weeks.

This medicine is intended for:

1) neonates whose mothers are carriers of HBs antigen,
2) children with body mass of up to 50 kg especially exposed to HBV infection at the hospital.

2. What you need to know before you use GAMMA anty-HBs 200

Do not use GAMMA anty-HBs 200

- if you are allergic to human immunoglobulin or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using GAMMA anty-HBs 200.

GAMMA anty-HBs must not be administered intravenously.

Ensure that GAMMA anty-HBs 200 is not administered into a blood vessel, because of the risk of shock.

If the recipient is a carrier of HBsAg, there is no benefit in administering this product.

Hypersensitivity

True hypersensitivity reactions are rare.

GAMMA anty-HBs 200 contains a small quantity of IgA. Individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of blood components containing IgA. The physician must therefore weigh the benefit of treatment with GAMMA anty-HBs 200 against the potential risk of hypersensitivity reactions.

Rarely, human hepatitis B immunoglobulins can induce a fall in blood pressure with anaphylactic reaction, even in patients who have tolerated previous treatment with human immunoglobulin.

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented.

Effect on blood tests results

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

Passive transmission of antibodies to erythrocyte antigens, e.g. A, B, D may interfere with some serological tests for red cell antibodies, for example the antiglobulin test (Coombs' test).

Infectious agents

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as HAV and/or parvovirus B19.

There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

It is strongly recommended that every time that GAMMA anty-HBs 200 is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Other medicines and GAMMA anty-HBs 200

Tell your doctor if you are taking, have recently taken or might take any other medicines. This medicine may impair the effect of some live attenuated virus vaccines such as measles, rubella and mumps. After receiving immunoglobulins vaccination with these vaccines should be performed after 3 months.

When laboratory tests are performed inform the doctor about taking immunoglobulins as this may affect the results of serological tests.

Pregnancy, breast-feeding and fertility

Pregnancy

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and therefore the product should be used with caution in pregnant or lactating women. It was demonstrated that immunoglobulins penetrate through the placenta, which is increased in the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Breastfeeding

Immunoglobulins are secreted into mother's milk and may contribute to the protection of the newborn against pathogens that penetrate through mucous membranes.

Fertility

Clinical experience with immunoglobulin use indicates that no harmful effect on fertility should be expected.

Driving and using machines

The medicine has no influence on the ability to drive and use machines.

3. How to use GAMMA anty-HBs 200

Always take this medicine exactly as your doctor has told you. The medicine is intended for intravenous administration by the doctor or nurse. This medicine should be brought to room or body temperature before use. The doctor or nurse should check if the solution in the ampoule is clear or slightly opalescent. Solutions that are cloudy or have deposits must not be used.

GAMMA anty-HBs 200 is intended for intravenous administration to:

1) neonates whose mothers had hepatitis B infection during pregnancy or are HBs antigen carriers are administered 200 IU no later than up to 12 hours after birth,

2) neonates who were not vaccinated against hepatitis B; after 1 month of the first dose (200 IU) the second dose of 200 IU is administered,

3) children with body mass of up to 50 kg are administered according to the following regimen:
   - neonates, infants and children with body mass of up to 10 kg are administered 200 IU (contents of 1 ampoule),
   - children with body mass of 10 kg to 20 kg are administered 400 IU (contents of 2 ampoules),
   - children with body mass of 20 kg to 30 kg are administered 600 IU (contents of 3 ampoules),
   - children with body mass of 30 kg to 50 kg are administered 800 IU (contents of 4 ampoules).

   In case of child's long-term stay at the hospital the dose is repeated every 3-4 weeks.

In all these situations, vaccination against hepatitis B virus is highly recommended. The first vaccine dose can be injected the same day as human hepatitis B immunoglobulin, however in different sites.

If dose higher than 400 IU (contents of more than 2 ampoules) is used, the product should be administered intramuscularly in different parts of the body in divided doses.

When simultaneous vaccination is necessary, the immunoglobulin and the vaccine should be administered at two different sites.
In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination, and for whom continuous prevention is necessary, administration of 500 IU to adults and 8 IU/kg to children every 2 months can be considered; a minimum protective antibody titre is considered to be 10 IU/mL.

If intramuscular administration is contraindicated (bleeding disorders), the injection can be administered subcutaneously if no intravenous product is available. However, it should be noted there are no clinical data regarding efficacy of the subcutaneous administration of GAMMA anty-HBs 200.

Any unused product or waste material should be disposed of in accordance with local regulations.

4. Possible side effects

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

The following side effects were rare (concerns 1 to 10 in 10,000 patients):
headache, lowered blood pressure, nausea, vomiting, skin reactions, erythema, itching, joint ache, fever, malaise, shivers; injection site reactions: swelling, pain, erythema, hardening, warmth, itching, rash.

The following side effects were very rare (concerns less than 1 in 10,000 patients):
hypersensitivity, anaphylactic shock.

Frequency of the following effects is not known (cannot be estimated from the available data):
tachycardia.

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. You can also report side effects directly to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:
Al. Jerozolimskie 181C, 02-222 Warszawa, Phone: 22 49-21-301, fax: 22 49-21-309, web page: https://smz2.ezdrowie.gov.pl.
Adverse reactions can be also reported to marketing authorization holder.
By reporting side effects you can help provide more information on the safety of this medicine.

See section 2 for safety information with reference to infectious agents.

5. How to store GAMMA anty-HBs 200

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the packaging.
The expiry date refers to the last day of that month.
Store in a refrigerator (2°C – 8°C).
Protect from light.
Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
Batch number (Lot)
Expiry date (EXP)

6. Contents of the pack and other information

What GAMMA anty-HBs 200 contains

- The active substance of GAMMA anty-HBs 200 is human hepatitis B immunoglobulin

1 ml of the solution contains human protein not less than 100 mg, of which at least 85% is immunoglobulin G (IgG) with anti-HBs antibody content 200 IU.

- The other ingredients (excipients) are: glycine, sodium chloride, water for injections

What GAMMA anty-HBs 200 looks like and contents of the pack

GAMMA anty-HBs 200 is a clear or slightly opalescent solution.

A single pack contains 1 ampoule of 1 ml.

Marketing Authorisation Holder and Manufacturer

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