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## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### GAMMA anti-HBs 1000

Immunoglobulinum humanum hepatitis B Human immunoglobulin against Hepatitis B  
Solution for injections

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 pharmacist. - 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 any of the side effects gets serious, or if you notice any side effects, including not listed in this leaflet, please tell your doctor.

What is in this leaflet: 1. What Gamma anti-HBs 1000 is and what it is used for 2. Before you use Gamma anti-HBs 1000 3. How to use Gamma anti-HBs 1000 4. Possible side effects 5. How to store Gamma anti-HBs 1000 6. Contents of the pack and other information

1. What Gamma anti-HBs 1000 is and what it is used for Gamma anti-HBs is a solution for intramuscular injections containing 1000 IU of anti-HBs antibodies in an aqueous solution. When administered prophylactically, the medicine prevents infection with the virus of Hepatitis B (HBV). Anti-HBs immunoglobulins administered intramuscularly in the case of infection bind the HBs antigen and prevent Hepatitis B. Passive immunity lasts for approx. 3 to 4 weeks. The product is intended for: 1) adults and children not vaccinated against Hepatitis B and especially exposed to the risk of HBV nosocomial infection, 2) medical personnel not vaccinated against Hepatitis B, following exposure to HBV including: needle stick injury in a cut, wound contamination or contamination through mucous membranes, 3) sexual partners of patients with acute Hepatitis B

2. What you need to know before you use Gamma anti-HBs 1000 Do not use Gamma anti-HBs 1000 Contraindications for use include:  hypersensitivity to human immunoglobulin, especially in patients with immunoglobulin A deficiency and circulating anti-IgA antibodies,  known hypersensitivity to any of the product components.

Warnings and precautions Gamma anti-HBs 1000 must not be administered intravenously.

Make sure Gamma anti-HBs 1000 is not administered directly to a blood vessel due to the risk of shock.

If the recipient carries HBsAg, product administration does not produce any benefits.

Hypersensitivity reactions occur seldom.

Sometimes, human immunoglobulin against Hepatitis B evokes a drop in blood pressure combined with anaphylactic reactions even, in the case of patients who tolerated previous treatment with human immunoglobulin.

In the case of suspected allergic or anaphylactic reaction, product injection should be discontinued immediately. In the case of shock, a standard medical procedure should be followed.

Gamma anti-HBs 1000 is derived from human plasma collected from donors with a high level of antiHBs antibodies. The manufacturing technique is based on the fractionation of plasma with cold ethyl alcohol according to the Cohn procedure. In the case of administration of products obtained from human blood or plasma, the transmission of infectious agents cannot be completely excluded. This refers also to pathogens and viruses unknown before. However, the risk of transmitting infectious agents is minimised by: □ selection of donors based on clinical anamnesis and testing of both, a single plasma unit and pooled plasma for the presence of HBsAg, anti-HIV and anti-HCV antibodies. □ testing of pooled plasma for the presence of the genetic material from the virus of hepatitis type C (HCV). □ applied inactivation/elimination of viruses in the manufacturing process, validated using model viruses. Undertaken safety measures which are considered as efficient apply to enveloped viruses, such as: HIV, HBV and HCV. However, they can have a limited efficiency for non-enveloped viruses, such as virus of hepatitis type A (HAV) and/or parvovirus B19. Clinical data exists confirms lack of transfer of hepatitis A virus (HAV) and B19 parvovirus during immunoglobulin use. Also, the presence of antibodies is presumed to play an important role for viral safety of the product.

It is recommended, for patient's safety, as far as possible, to record the name and lot number of the Gamma anti-HBs 1000 product together with the patient data after each application of the medicine, in order to correlate the product lot number to a given patient.

Other medicines and Gamma anty-HBs 1000 You should inform your physician of any medications you have recently taken, even those not subject to medical prescription. The product may impair efficiency of vaccines containing live attenuated viruses, i.e. measles, rubella, mumps. The administration of immunoglobulin should be followed by a 3-month pause before such vaccinations. If any laboratory tests are performed, tell your doctor about taking immunoglobulin, because this may affect the results of serological tests.

**Pregnancy and breast-feeding** The product can be used by pregnant and breast-feeding women.

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**Driving and using machines** No effects on ability to drive and use machines exist.

**3. How to use Gamma anty-HBs 1000** The medicine should be taken as prescribed by the doctor. Gamma anty-HBs 1000 should be administered intramuscularly: 1) adults and children weighing 50 kg and more: 1000 IU is administered, and in the case of a long hospital stay the dose (1000 IU) is repeated every 3-4 weeks, 2) medical personnel: 1000 IU as soon as possible, however within max. 48 hours after exposure to HBV and another dose of 1000 IU after 4 weeks, provided that a series of vaccinations against Hepatitis B has not already been started, 3) sexual partners of patients with acute Hepatitis B: 1000 IU as soon as possible, within max. 14 days after occurrence of Hepatitis B in the partner, and another dose of 1000 IU after 4 weeks, provided that a series of vaccinations against Hepatitis B has not already been started.

In such situations, vaccination against Hepatitis B is highly recommended. The first dose of the vaccine can be administered on the same day as human immunoglobulin against Hepatitis B, however in different sites.

If contraindications for intramuscular injections exist (coagulation impairment), the product can be administered subcutaneously, provided that no product for intravenous administration is available. It should be noted, however, that no clinical data about efficiency of subcutaneous administration of Gamma anty-HBs 1000 is available.

The product should be administered in an intramuscular injection by a physician or nurse. The product should be brought to room or body temperature before use. The physician or nurse should check whether the solution in an ampoule is clear or slightly opalescent. Do not use solutions that are cloudy or have deposits. Any unused product or waste material should be disposed of in accordance with local regulations.

4. Possible side effects Like all medicines, Gamma anti-HBs 1000 can cause side effects, although not everybody gets them. There is no sufficient clinical data about the frequency of occurrence of side effects. The following side effects have been observed:

Classification of systems and organs compliant with MedDRA system

Side effects Frequency

Immune system disorders Hypersensitivity, anaphylactic shock

very rare (<1/10 000 including isolated cases) Nervous system disorders Headaches rare (>1/10 000 <1/1 000)

Cardiac disorders Tachycardia No data available Vascular disorders Lower blood pressure rare (>1/10 000 <1/1 000)

Gastrointestinal disorders Nausea, vomiting rare (>1/10 000 <1/1 000)

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Skin and subcutaneous tissue disorders

Skin reactions, erythema, pruritus

rare (>1/10 000 <1/1 000)

Musculoskeletal and connective tissue disorders

Arthralgia rare (>1/10 000 <1/1 000)

General disorders and conditions at the site of injection

Fever, ill-being, shivers rare (>1/10 000 <1/1 000)

At the injection site: oedema, pain, erythema, induration, burning sensation, pruritus, rash

rare (>1/10 000 <1/1 000)

Viral safety, see section 2.

5. How to store Gamma anti-HBs 1000 Keep out of the reach and sight of children. Do not use this medicine after the expiry date which is stated on the pack. Store at 2°C - 8°C (in a refrigerator). Keep away from light. Lot number Expiry date (EXP)

6. Contents of the pack and other information What Gamma anti-HBs 1000 contains One ampoule with the solution contains: Human immunoglobulin against Hepatitis B 1000 IU  
Excipients: glycine, sodium chloride, water for injections

What Gamma anti-HBs 1000 looks like and contents of the pack

What Gamma anti-HBs 1000 looks like

Transparent or slightly opalescent solution.

Packaging 1.5 ml ampoule

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