

PACKAGE LEAFLET

Package leaflet: Information for the user

Human Hepatitis B Immunoglobulin 100 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, nurse or healthcare professional.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, nurse or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Human Hepatitis B Immunoglobulin is and what it is used for
2. What you need to know before you use Human Hepatitis B Immunoglobulin
3. How to use Human Hepatitis B Immunoglobulin
4. Possible side effects
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1. What Human Hepatitis B Immunoglobulin is and what it is used for

Human Hepatitis B Immunoglobulin contains the active ingredient human hepatitis B immunoglobulin. It is prepared from blood plasma from screened donors.

Human Hepatitis B Immunoglobulin is used in adults and children to protect from exposure to the hepatitis B virus. It is used to protect against infection by the hepatitis B virus and is normally given with hepatitis B vaccine. Hepatitis B is a virus which damages the liver and over time it can stop the liver from working properly. Your doctor will explain further why this medicine has been given to you.

This medicine is usually given to you if:

- you have not had previous vaccination, or have not been properly vaccinated to hepatitis B virus
- you have been accidentally exposed to infection by skin pricks, cuts, spillage into the eye or mouth, from infectious material such as blood, or from bites
- you are having kidney dialysis while waiting for a hepatitis B vaccination to be fully effective
- you have previously received hepatitis B vaccination, but it has not worked for you and you are at risk of infection

This medicine can also be given to newborn babies born to mothers who have the hepatitis B virus.

2. What you need to know before you use Human Hepatitis B Immunoglobulin

Do not use Human Hepatitis B Immunoglobulin if:

- you are allergic (hypersensitive) to Human Hepatitis B Immunoglobulin or any of the other ingredients of this medicine (listed in section 6)
- if you are known to have antibodies to immunoglobulin A and have had an allergic reaction
- you suffer from any blood disorders which interfere with blood clotting

Warnings and precautions

Talk to your doctor or nurse before you are given Human Hepatitis B Immunoglobulin.

- True allergic reactions to the medicine are rare when it is injected into the muscle as directed. Even if you have had this medicine before, you could still have a reaction. If this happens, urgent medical attention is needed (see also section 4).
- If you do not have enough immunoglobulin A (IgA deficiency) you may develop antibodies. If you know you have antibodies to IgA tell your doctor or nurse before you use this medicine.
- If you suffer from high blood pressure, diabetes, have a history of blood clots or problems with your veins or arteries or a blood related disorder, tell your doctor or nurse before using this medicine.
- If you have recently had any vaccinations or know you are going to have any vaccinations, tell your doctor or nurse.
- If you develop pain, swelling, unusual warmth of a limb, sudden shortness of breath and chest pain worsening on deep breathing, numbness or weakness on one side, difficulty speaking or confusion, talk to you doctor or nurse immediately as you may have a blood clot.
- Tell your doctor or nurse if you are having any blood tests. This medicine will raise the level of some antibodies in your blood for several weeks. If you require a blood test during this period, tell your doctor or nurse when you last had this medicine injected as misleading results may occur with different tests.

If you are HBs antigen positive you will not receive Human Hepatitis B Immunoglobulin since there is no benefit in administering this medicine to you. Your doctor, nurse or healthcare professional will be able to explain this to you.

Viral safety

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- the testing of each donation and pools of plasma for signs of virus/infections
- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus and parvovirus B19 viruses.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product are protective.

It is strongly recommended that every time you receive a dose of Human Hepatitis B Immunoglobulin, the name and batch number of the product are recorded to maintain a record of the batches used.

Children and adolescents

The listed warnings and precautions apply to both adults and children.

Other medicines and Human Hepatitis B Immunoglobulin

Tell your doctor, nurse or healthcare professional if you are using, have recently used or might use any other medicines.

Vaccinations

Human Hepatitis B immunoglobulin provides you with a range of antibodies. These antibodies will interfere with the response to some vaccines, especially MMR (measles, mumps and rubella) and varicella (chickenpox) vaccines. If you are given Human Hepatitis B Immunoglobulin injection within 3 months of receiving these vaccines, tell your doctor, as this medicine can affect those vaccines from working properly. You may need to receive another vaccine 3 months after using Human Hepatitis B Immunoglobulin.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or healthcare professional for advice before taking this medicine.

Driving and using machines

Human Hepatitis B Immunoglobulin has no influence on the ability to drive and use machines

Human Hepatitis B Immunoglobulin contains sodium

200 IU Vial: This medicine contains approximately 0.4 mmol (9 mg) sodium per 200 IU vial, that is to say essentially 'sodium-free'.

500 IU Vial: This medicine contains approximately 1 mmol (23 mg) sodium (main component of cooking/table salt) in each 500 IU vial. This is equivalent to 1% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Human Hepatitis B Immunoglobulin

Your doctor, nurse or healthcare professional will inject Human Hepatitis B Immunoglobulin into a muscle. Your doctor, nurse or healthcare professional will decide how much to give you.

If you use more Human Hepatitis B Immunoglobulin than you should

If you are given more Human Hepatitis B Immunoglobulin than recommended, your doctor, nurse or healthcare professional may carry out some blood tests. It is not known what effects an overdose would have.

If you have any further questions on the use of this medicine, ask your doctor, nurse or healthcare professional.

4. Possible side effects

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

If you feel unwell, tell your doctor immediately. Side effects may occur even if you have previously received human immunoglobulins and tolerated them well.

The following side effects have been reported with the Human Hepatitis B Immunoglobulin:

Not known (frequency cannot be estimated from the available data):

- severe allergic reactions (anaphylactic shock)
- hypersensitivity reactions
- low blood pressure
- injection site swelling, soreness, warmth, redness, itching, bruising or hardening of the skin
- headache
- dizziness
- fast heart rate

- vomiting
- nausea
- feeling sick (malaise)
- skin (cutaneous) reactions such as erythema (redness), itchy skin
- joint pains, back pain
- fever
- tiredness
- chills

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Human Hepatitis B Immunoglobulin

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 containers after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Short periods (up to 1 week) of storage at room temperature (up to 25°C) in the dark, will not damage the product.

Keep the vials in the outer carton to protect from light.

Do not use this medicine if you notice small bits in the dissolved product.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or doctor how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Human Hepatitis B Immunoglobulin contains

- The active substance is human hepatitis B immunoglobulin
- The excipients are: sodium chloride, glycine, sodium acetate trihydrate and sodium hydroxide (for pH adjustment).

What Human Hepatitis B Immunoglobulin looks like and the contents of the pack

Human Hepatitis B Immunoglobulin is a colourless to pale yellow sterile solution available as single dose vials containing either 200 IU or 500 IU in glass vials with a closure to prevent tampering.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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