Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

Hebagam® IM, 200 IU (100 IU/ml), solution for injection

Human hepatitis B immunoglobulin

Sugar free

Read all of this leaflet carefully before you are given Hebagam IM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

  Hebagam IM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What Hebagam IM is and what it is used for
2. What you need to know before you are given Hebagam IM
3. How to receive Hebagam IM
4. Possible side effects
5. How to store Hebagam IM
6. Contents of the pack and other information

1. What Hebagam IM is and what it is used for

What Hebagam IM is

Hebagam IM is a solution for injection that contains proteins isolated from human plasma. These proteins belong to the biological class of medicines called immunoglobulins, also known as antibodies.

Hebagam IM contains the active ingredient human hepatitis B immunoglobulin, which is a specific antibody that works against the hepatitis B virus**.**

It is prepared from human plasma from healthy donors that have a high quantity of these antibodies.

What Hebagam IM is used for

Hebagam IM is used to protect against infection caused by the hepatitis B virus. It is usually given:

- If you have not had previous vaccination, or have not been properly vaccinated, to hepatitis B, and 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.
- To newborn babies whose mother has hepatitis B infection.
- If you have been in sexual contact with someone who has hepatitis B infection.
- If you are having kidney dialysis while waiting for vaccination to be fully effective.

If you have not responded to hepatitis B vaccination, but you remain at risk of infection, perhaps because of your job.

2. What you need to know before you are given Hebagam IM

Hebagam IM should not be administered to you:

- If you are hypersensitive (allergic) to human hepatitis B immunoglobulin or any of the other ingredients in Hebagam IM (listed in section 6).
- If you are hypersensitive to human immunoglobulins.

Your doctor will decide if you should be given this medicine in this case.

Warnings and precautions

Hebagam IM must not be administered into a vein.

It is not suitable for the treatment of any type of hepatitis B infection.

Tell your doctor or health care provider before being given the injection:

- If you have had a severe allergic reaction to plasma products.
- If you are suffering from any bleeding disorders which interfere with clotting.
- If you have specifically low levels of immunoglobulin A (IgA) as the small amounts of IgA in this preparation may cause an allergic reaction the next time you are given this medicine.

Your doctor will decide if you should be given this medicine in these cases.

Special care should be taken with Hebagam IM*:*

- True hypersensitivity reactions are rare but allergic type reactions may occur. Tell your doctor or health care provider immediately in case of suspected allergy or serious allergic (anaphylactic) reactions. Your doctor will monitor you closely and will have medication available to treat you if there are any signs of an allergic reaction to Hebagam IM.
- If you are going for a blood test, as this medicine may lead to misleading results. Tell your health care provider if this is the case.
- Hebagam IM is not recommended if you are a person continuously exposed to the risk of hepatitis B infection, for example if you are working in a laboratory, receiving chronic dialysis, travelling to areas where hepatitis B is common or if you live in a care institution. Vaccination against hepatitis B is preferable in these cases.

Virus safety

Human hepatitis B immunoglobulin is prepared from human plasma.

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 (HBV) and hepatitis C virus (HCV).

The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and parvovirus B19.

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.

Traceability

It is strongly recommended that when you receive a dose of Hebagam IM, the name and batch number of the product are recorded in order to maintain a record of the batch used.

Please speak to your health care provider should you require additional information in this regard.

Other medicines and Hebagam IM:

Hebagam IM should not be mixed with other medicines for injection when being given to you.

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

Vaccinations

Tell your doctor or health care provider prior to starting Hebagam IM treatment if you have had a vaccination within the last 3 to 4 weeks. Live virus vaccines (e.g. measles, mumps, varicella or rubella) should also not be given for 3 months after you were last given Hebagam IM, as the effectiveness of such vaccinations may be reduced.

Hebagam IM with food and drink:

Hebagam IM is injected directly into the muscle and is not affected by food or drink.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Driving and using machines

You may experience dizziness and other side effects when you receive Hebagam IM.

It is not always possible to predict to what extent Hebagam IM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Hebagam IM affects you.

3. How to receive Hebagam IM

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Hebagam IM. It will be given to you by a person who is qualified to do so.

Hebagam IM is for intramuscular use only must never be injected into a vein due to the risk of shock.

It must be injected slowly into a large muscle (like the arm or thigh) different from the one in which you were given the vaccine.

Human hepatitis B immunoglobulin does not work if you already have hepatitis B. A blood test to see whether you have the infection may be done before injection.

However, the injection should not be delayed for more than 48 hours after you have been exposed to a possible hepatitis B infection. In any case, the dose should be given within one week after exposure to the infection.

Doses:

After accidental exposure to possible hepatitis B infection:

Adults: The dose is at least 500 IU

Children: 10 years to adult: 500 IU (5 ml)

5 to 9 years (inclusive): 300 IU (3 ml)

Birth to 4 years (inclusive): 200 IU (2 ml)

A second dose may be given 4 weeks later. Your doctor will advise you on the correct dose for you and whether you need a second dose.

On kidney dialysis: A dose of 8 to 12 IU/kg body weight (maximum 500 IU) is given every 2 months while waiting for vaccination to become fully effective.

Newborns whose mother has hepatitis B infection: A dose of 200 IU is given, preferably at birth, or within 48 hours after birth. The first dose of hepatitis B vaccine may be given at the same time.

Within one week of sexual contact with a person with hepatitis B infection, the dose is at least 500 IU.

In all of these cases vaccination against hepatitis B virus is strongly recommended.

If you receive more Hebagam IM than you should:

Your dosage is calculated by your doctor but if you feel unwell after being given this medicine, you should consult your doctor.

Since a health care provider will administer Hebagam IM he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you missed a dose of Hebagam IM

Since a health care provider will administer Hebagam IM, it is unlikely that the dose will be missed.

4. Possible side effects

Hebagam IM can have side effects.

Not all side effects reported for Hebagam IM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving Hebagam IM, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Allergic reaction
- Faintness

These are all very serious side effects. If you have them, you may have had a serious reaction to Hebagam IM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects with unknown frequency:

- Headache
- Flushing
- Nausea
- Skin reactions
- Back pain
- Administration site reaction or injection site pain
- Fever
- Chills

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (https://primaryreporting.who-umc.org/ZA) found on SAHPRA website or to National Bioproducts Institute NPC via the email address Pharmacovigilance@nbisa.org.za. By reporting side effects, you can help provide more information on the safety of Hebagam IM.

5. How to store Hebagam IM

Store all medicines out of reach of children.

- Store between 2 °C and 8 °C (in a refrigerator).
- Do not freeze.
- Protect from light.
- Keep the ampoule in the outer carton until required for use.
- Do not use after the expiry date stated on the label.

Disposal:

After injection of the correct dose, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers, according to correct procedures. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Hebagam IM contains

- The active substance is a sterile solution of 200 IU (100 IU/ml) human hepatitis B immunoglobulin (antibodies)
- The other ingredients are glycine, sodium chloride, sodium hydroxide, hydrochloric acid, human albumin, human normal immunoglobulin and water for injections.
- Hebagam IM does not contain any preservatives.

What Hebagam IM looks like and contents of the pack

Hebagam IM is a solution for injection.

The sterile solution is a clear liquid, with a slightly turbid/cloudy appearance, which is almost colourless or pale yellow to light brown.

Hebagam IM is packed in a sterile, clear, colourless, 2 ml glass ampoule marked with a yellow ring.

Holder of Certificate of Registration

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