Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

Rabigam® IM, 300 IU (150 IU/ml), solution for injection

Human rabies immunoglobulin

Sugar free

Read all of this leaflet carefully before you are given Rabigam 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.
- Rabigam 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 Rabigam IM is and what it is used for
2. What you need to know before you are given Rabigam IM
3. How to receive Rabigam IM
4. Possible side effects
5. How to store Rabigam IM
6. Contents of the pack and other information

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

What Rabigam IM is

Rabigam 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.

Rabigam IM contains the active ingredient human rabies immunoglobulin, which is a specific antibody that works against the rabies virus**.**

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

What Rabigam IM is used for

Rabigam IM is used to protect against rabies if you have been exposed or suspected to have been exposed to the rabies virus.

It is usually given if you have been bitten, scratched or sustained any other injury from a suspected rabid animal or you may have swallowed or breathed in tissue, such as saliva, from a suspected rabid animal.

If you have previously had the rabies vaccine and your antibody levels have recently been confirmed as sufficient, you will be given the vaccine only.

Your doctor or other health care provider will tell you if it is advisable for you to have this medicine.

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

Rabigam IM should not be administered to you:

If it can be shown that you already have sufficient antibodies to protect against the virus.

Warnings and precautions

Rabigam IM must not be administered into a vein.

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.
- If you have received rabies vaccine treatment, repeated doses of rabies immunoglobulin should not be given.

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

Special care should be taken with Rabigam 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 Rabigam IM.
- If you are going for a blood test, as this medicine may lead to misleading results. Tell your **[**~~doctor~~**]** health care provider if this is the case.

Virus safety

Human rabies 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 Rabigam 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 Rabigam IM:

Rabigam 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

Human rabies immunoglobulin (antibodies) may interfere with the response to some live virus vaccines, especially mumps, rubella and varicella (chickenpox) vaccines. These vaccines should not be given for 3 months after you were last given Rabigam IM, as the effectiveness of such vaccinations may be reduced.

Rabigam IM with food and drink:

Rabigam 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 Rabigam IM.

It is not always possible to predict to what extent Rabigam 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 Rabigam IM affects you.

3. How to receive Rabigam IM

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

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

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

It should be injected into and around the wound.

Your doctor will ensure that the wound has been adequately filled with the injection before stitching it up (if required). Any remainder immunoglobulin should be injected slowly, deep into a large muscle, different from the one in which you were given the vaccine, like the upper arm in adults or side of the thigh in children.

Doses:

Rabigam IM must be given as soon as possible after you have been exposed or suspected to have been exposed to the rabies virus. The usual dose for adults and children is 20 IU per kilogram body mass given at the same time as the first dose of the rabies vaccine, or soon after, but not later than 7 days after the vaccine. Repeat doses of Rabigam IM should not be given once treatment with rabies vaccine has started as this could prevent full development of active immunity from the vaccine.

Waiting for test results from the suspected rabid animal should not delay your treatment but if no rabies virus is found in the animal, treatment should be stopped.

If you receive more Rabigam 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 Rabigam 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 Rabigam IM

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

4. Possible side effects

Rabigam IM can have side effects.

Not all side effects reported for Rabigam IM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving Rabigam 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 Rabigam 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 Rabigam IM.

5. How to store Rabigam 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 Rabigam IM contains

- The active substance is a sterile solution of 300 IU (150 IU/ ml) human rabies immunoglobulin (antibodies).
- The other ingredients are glycine, sodium chloride, sodium hydroxide, hydrochloric acid, human hepatitis B immunoglobulin, human albumin, human normal immunoglobulin and water for injections.
- Rabigam IM does not contain any preservatives.

What Rabigam IM looks like and contents of the pack

Rabigam 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.

Rabigam IM is packed in a sterile, clear, colourless, 2 ml glass ampoule marked with an orange ring.

Holder of Certificate of Registration

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