Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

Rhesugam IM, 500 IU (100 micrograms)/2 ml (solution for injection)

Human anti-D (Rh) immunoglobulin

Sugar free

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

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

What Rhesugam IM is

Rhesugam 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.

Rhesugam IM contains the active ingredient human anti-D (Rh) immunoglobulin, which is a specific antibody that prevents active immunisation to the D (Rh) erythrocyte antigen in Rh-negative individuals exposed to Rh-positive blood.

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

What Rhesugam IM is used for

During pregnancy, small amounts of blood from the baby may leak into the mother's circulation. If the mother is blood type Rhesus-negative (Rh-negative) and the baby's blood type Rhesus-positive (Rh-positive), the mother would develop antibodies against the baby's red blood cells, and destroy the blood cells.

Rhesugam IM is used to prevent Rhesus-negative blood-type women of child-bearing age becoming sensitised (reactive) to Rh-positive red blood cells, to protect a Rh-positive baby's red blood cells from being destroyed, either during the current pregnancy or, more particularly, in future pregnancies.

It should be used:

- Soon after any incident or intervention during pregnancy which might lead to bleeding across the placenta;
- As a routine preventative measure during pregnancy (usually at 28 and/or 34 weeks);
- Soon after an abortion when sensitisation is possible;
- Soon after giving birth to a baby whose red blood cells are Rh-positive;
- Soon after blood components containing Rh-positive red blood cells have been given, for any reason, even when you are not pregnant.

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 Rhesugam IM

Rhesugam IM should not be administered to you:

- If you are hypersensitive (allergic) to human anti-D (Rh) immunoglobulin or any of the other ingredients in Rhesugam 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

Rhesugam IM must not be administered into a vein.

It is not effective once the mother has formed anti-D antibodies.

This medicine should not be given to:

- The newborn baby;
- A Rh-positive mother;
- A Rh-negative mother who has given birth to a Rh-negative baby;
- A Rh-negative mother who has been previously sensitised to the D (Rh) erythrocyte antigen.

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 Rhesugam 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 Rhesugam IM.
- If you are being treated with Rhesugam IM after an incompatible transfusion, you may receive large amounts of the medicine. In this case rupture of red blood cells (haemolytic reaction) may occur. For this reason, your health care provider will monitor you closely and may need to do blood tests.
- 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 anti-D 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 Rhesugam 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 Rhesugam IM:

Rhesugam IM should not be mixed with other medicine 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 Rhesugam IM treatment if you have had a vaccination within the last 2 to 4 weeks. Live virus vaccines (e.g. measles, mumps or rubella) should also not be given for 3 months after you were last given Rhesugam IM, as the effectiveness of such vaccinations may be reduced.

Rhesugam IM with food and drink:

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

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

This medicine is meant for use in pregnancy, if required, and can be used during breastfeeding.

Fertility

No data are available.

For patients receiving Rhesugam IM for incompatible transfusion

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 Rhesugam IM.

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

3. How to receive Rhesugam IM

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

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

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

If the medicine is injected into fat rather than muscle, less may circulate in your body therefore it must be injected slowly into a large muscle (like the upper arm).

The injection should be administered as soon as it is convenient after an incident or intervention during pregnancy and after delivery (ideally within 72 hours). Injection of this medicine should be as close to the time of the incident as possible.

Doses:

The amount of Rhesugam IM you require is related to the estimated amount of Rh (D) antigen in the Rh-positive cells to which you have been exposed. A special test called the Kleihauer-Betke test may be done to accurately determine the amount of foetal cells in the mother's circulation.

The recommended doses of Rhesugam IM are:

Preventative measures before birth:

500 IU at 28 and/or 34 weeks of pregnancy. If the baby is Rh-positive, a similar or higher dose should be given after delivery.

Following an incident or intervention during pregnancy:

Up to 20 weeks pregnancy, the recommended dose is 250 IU.

After 20 weeks, the recommended dose is 500 IU. Occasionally more may need to be given.

Following birth:

The recommended dose is 500 IU. Occasionally more may need to be given.

Prevention of Immunisation/Protection in Rh-negative woman of child-bearing age given platelet transfusion containing Rh-positive red cells:

250 IU for each dose of platelets (i.e. 5-6 units) from Rh-positive donors; or 500 IU if more than 10 units are received.

Transfusion of Rh blood that is not compatible with yours:

The dose is calculated to clear the amount of red cells you received and is usually 125 IU per ml of red cells.

If you receive more Rhesugam IM than you should:

Your dose 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 Rhesugam 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 Rhesugam IM

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

4. Possible side effects

Rhesugam IM can have side effects.

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

These are all very serious side effects. If you have them, you may have had a serious reaction to Rhesugam 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
- Dizziness
- High heart rate (Tachycardia)
- Low blood pressure
- Flushing
- Nausea
- Vomiting
- Skin reaction
- 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 healthcare 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 the 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 Rhesugam IM.

5. How to store Rhesugam 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 Rhesugam IM contains

- The active substance is a sterile solution of 500 IU (100 micrograms/ 2 ml) human anti-D (Rh) 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.
- Rhesugam IM does not contain any preservatives.

What Rhesugam IM looks like and contents of the pack

Rhesugam 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.

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

Holder of Certificate of Registration

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