Rhophylac®

Human Anti-D (Rh_0) Immunoglobulin solution for injection in pre-filled syringe

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rhophylac®. It does not contain complete information about Rhophylac®. It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Rhophylac® is used for

What is Rhophylac®?

Rhophylac® is a ready-to-use solution for injection, which comes in a pre-filled syringe. The solution contains special proteins, isolated from human blood plasma. These proteins belong to the class of so called 'immunoglobulins', also called antibodies. The active ingredient of Rhophylac® is a specific antibody called 'anti-D (Rh) immunoglobulin'. This antibody works against Rhesus factor type D.

What is Rhesus factor type D?

Rhesus factors are special characteristics of human red blood cells. About 85% of the population carry the so called Rhesus factor type D (abbreviated 'Rh(D)'). These people are called Rh(D)-positive. People who do not carry Rhesus factor type D are called Rh(D)-negative.

What is anti-D (Rh) immunoglobulin?

Anti-D (Rh) immunoglobulin is an antibody, which works against Rhesus factor type D and is produced by the human immune system. When a Rh(D)-negative person receives Rh(D)-positive blood, her/his immune system will recognise the Rh(D)-positive red blood cells as 'foreign' to her/his body, and will attempt to destroy them. For this purpose, the immune system will build specific antibodies against Rhesus factor type D. This process is called 'immunisation' and it usually takes some time (2-3 weeks). Therefore, the Rh(D)-positive red blood cells will not be destroyed upon the first contact, and no signs or symptoms are usually seen then. But when the same Rh(D)-negative person receives Rh(D)-positive blood a second time, the antibodies will be 'ready at hand' and her/his immune system will destroy the foreign red blood cells immediately.

How Rhophylac® works

If a Rh(D)-negative person is given a sufficient amount of human anti-D (Rh) immunoglobulin, immunisation against Rhesus factor type D can be prevented. To achieve this, treatment with Rhophylac® should commence before or early enough after the first contact to Rh(D)-positive red blood cells. The anti-D (Rh) immunoglobulins contained in Rhophylac® will then destroy the foreign Rh(D)-positive red blood cells immediately. Thus, the person's immune system will not be prompted to build-up its own antibodies.

When is Rhophylac® used

Rhophylac® is used in two distinct situations:

a. You are a Rh(D)-negative pregnant woman, who carries a Rh(D)-positive baby.
   In this special situation you may be immunised by red blood cells from your baby passing over into your own blood circulation. If this happens, the first baby is not usually affected and fully healthy. But in the next Rh(D)-positive baby, the mother's antibodies would destroy the baby's red blood cells already during pregnancy. This may lead to complications with the baby, including his/her possible death.
   As a Rh(D)-negative pregnant woman, you may receive anti-D (Rh) immunoglobulins in the following situations:
   - when you carry or have just delivered a Rh(D)-positive baby
   - when you lose a Rh(D)-positive baby (miscarriage, threatened miscarriage or abortion)
   - when your pregnancy is severely complicated (ectopic pregnancy or hydatidiform mole)
   - when it is likely that your baby's red blood cells have

passed over into your own blood circulation (transplacental haemorrhage resulting from antepartum haemorrhage). This may, for example, happen when you experience vaginal bleedings during pregnancy
- when your doctor needs to perform testing methods for foetal deformities (amniocentesis, chorionic biopsy)
- when your doctor or midwife needs to try moving the baby from outside (e.g. external version of the baby or other obstetric manipulative procedures)
- when you have an accident hurting your stomach or gut (abdominal trauma).

b. You are a Rh(D)-negative person, who has accidentally received infusions (transfusions) of Rh(D)-positive blood (mismatched transfusion). This also applies to any blood products containing Rh(D)-positive red blood cells.

Before you are given Rhophylac®

Rhophylac® must not be used if you have a history of allergy to this product. Tell your doctor if you have allergies to any other medicines or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- have a blood type Rh(D)-positive
- have a blood type Rh(D)-negative but have been previously exposed to Rh(D)-positive blood
- are allergic to any of the components of the product
- have previously been advised that you have immunoglobulin A (IgA) deficiency
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores
- suffer from a blood disorder or blood clotting problem
- are pregnant or breast-feeding
- have had any vaccination during the last two weeks or intend to have any vaccination for the next three months
- have any other medical conditions.

Information on the starting material of Rhophylac®

Rhophylac® is made from human blood plasma (this is the liquid part of the blood).

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, and
- the testing of each donation and pools of plasma for signs of virus/infections.

Manufacturers of these products also include 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 and other types of infections.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this product with your doctor.

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 and parvovirus B19 viruses.

Immunoglobulins like Rhophylac® have not been associated with hepatitis A or parvovirus B19 infections. Rhophylac® also contains antibodies against hepatitis A or B19 virus and it is assumed that these antibodies contribute to the viral safety, too.

How Rhophylac® is used

Your doctor will give you Rhophylac® as an infusion, that is, an injection given slowly into the vein or it will be injected into the muscle. Your doctor will determine the dose(s) of Rhophylac® that you are to receive and which is the appropriate route of administration. If your body mass index (BMI) is greater or equal to 30 (calculated by dividing your body mass by the square of your height), the injection of Rhophylac® into a muscle may not be fully effective. In this case, your doctor or healthcare professional should inject this medicine into a vein.

If a large volume of product is required, you may receive more than one injection.

If you are treated with Rhophylac® after a mismatched transfusion, you may receive quite a large amount of the product (up to 3000 mg, equivalent to 20 mL or 10 syringes). In this case there is an increased risk for a special complication called haemolytic reaction. This results from the intended destruction of the foreign Rh(D)-positive red blood cells. For this reason your doctor or health care professional will monitor you closely and may need to do special blood tests.

If you want further information, consult your doctor.

Side effects

Along with their intended effects, blood products occasionally cause unwanted effects, some of which are serious. Furthermore, individual patients may react differently to the same dose of the same product. This applies to Rhophylac®.

Reactions to Rhophylac® are rare in Rh(D)-negative individuals. If Rhophylac® is given into a muscle, local pain and tenderness at the injection site may be felt.

Tell your doctor as soon as possible if you notice any of the following serious side effects:

- shortness of breath
- chest pain
- skin becoming yellow
- dark urine

In rare cases this type of medicine may cause a sudden fall in blood pressure or a condition called anaphylactic shock, which is an allergic reaction that has symptoms such as low blood pressure (feeling faint) and difficulty breathing.

Contact your doctor immediately if you experience any of the mentioned effects or any other abnormal signs after treatment.

Tell your doctor if you have any of these side effects:

- headache
- skin rashes
- itching
- fever
- chills
- nausea
- vomiting
- joint pain
- dizziness
- rapid heart beat (tachycardia)
- generally feeling unwell
- feeling very tired
- paleness of skin
- abdominal pain
- allergic reactions.

Rhophylac® may interfere with some live vaccines (e.g. measles, mumps, rubella or varicella), even up to three months later. Advise your doctor if you are to receive other vaccines within three months of receiving Rhophylac® or have just received a vaccine in the last two weeks.

Other side effects not listed above may also occur in some people. For a full list and explanation of the possible side effects associated with Rhophylac® please ask your doctor.

If you want further information consult your doctor.

Overdose

The consequences of overdose are not known.

Storing Rhophylac®

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Do not use after the expiry date shown on the label.

Further information

Rhophylac® can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about Rhophylac®. If you require further information about Rhophylac® and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

Product description

What it looks like

Rhophylac® is a solution for injection that is clear or opalescent. The product is supplied as a pre-filled syringe.

Ingredients

Each syringe of Rhophylac® contains a solution of gamma globulin (IgG) fraction of human plasma containing antibodies to Rh(D). It also contains glycine, sodium chloride and human albumin.

Distributor

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189-209 Camp Road
Broadmeadows VIC 3047
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Manufacturer

Rhophylac® is manufactured by CSL Behring AG, Switzerland.

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1500 IU (300 µg) per 2 mL AUST R 153815