

Package leaflet: Information for the user

Rhesonativ 625 IU/ml, solution for injection Human anti-D immunoglobulin

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rhesonativ is and what it is used for
2. What you need to know before you use Rhesonativ
3. How to use Rhesonativ
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1 What Rhesonativ is and what it is used for

Rhesonativ is an immunoglobulin and contains antibodies to the Rhesus factor. If a woman who lacks the Rhesus factor in her red blood cells (=Rh-negative) is pregnant with an unborn baby which has the Rhesus factor (=Rh-positive), her immune defence system may be stimulated to form antibodies to the Rhesus factor. These antibodies may harm her unborn baby, especially in subsequent pregnancies.

Rhesonativ is used to keep the Rh-negative woman from becoming immunised in the course of pregnancy and childbirth, and in this way prevent harm to the unborn baby. Rhesonativ is used in Rh-negative woman in case of:

- Anti-D prevention therapy for pregnant women who are RH- negative
- Delivery of a Rh-positive baby
- Abortion/threatened abortion (miscarriage/threatened miscarriage)
- Pregnancy outside the uterus, certain growths inside the uterus (mole), or bleeding of blood of the unborn baby into the normally separated maternal circulation or death of the unborn baby late in pregnancy

- Invasive procedures during pregnancy such as drawing of amniotic fluid with a syringe (i.e. amniocentesis), or blood sampling of the unborn baby from the umbilical vein, biopsy or obstetric manipulative procedures, e.g. procedures to manually rotate the baby to a correct position in the uterus, or belly trauma, surgical treatment of the unborn baby inside the uterus

Rhesonativ may also be used in Rh-negative individuals who have accidentally received an Rh-positive blood transfusion.

2 What you need to know before you use Rhesonativ

Do not use Rhesonativ:

- if you are allergic to human normal immunoglobulin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Rhesonativ.

Tell your doctor if you have any other illnesses.

Rhesonativ is neither intended for use in Rh(D)positive individuals nor for individuals already immunised to Rh(D) antigen.

True hypersensitivity reactions (allergic reactions) are rare, but may occur.

In case of suspected allergy or a serious allergic reaction (anaphylactic reaction), you should immediately inform your doctor or nurse. The symptoms are, for example, dizziness, palpitation of the heart, drop in blood pressure, difficulty breathing and swallowing, tightness of the chest, itching, generalised urticaria (hives), swelling of the face, tongue or throat, collapse and rash. Any of these conditions requires treatment immediately.

If you experience symptoms such as shortness of breath, pain and swelling of a limb, chest pain immediately contact your doctor or nurse as these may be signs of a blood clot.

Children

No data are available on the use in children.

Overweight patients

In case of overweight/obese patients the use of an intravenous anti-D product should be considered.

Virus 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.

The measures taken may be of limited value against non-enveloped viruses such as 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.

It is strongly recommended that every time you receive a dose of Rhesonativ, the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Rhesonativ

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- Rhesonativ may weaken the effect of vaccines such as measles, rubella, mumps and chicken pox. This is true for vaccines administered about 2-4 weeks prior to administration of an anti-D antibody injection as well as for vaccinations done afterwards. Following treatment with Rhesonativ, three months should be allowed to elapse before you are vaccinated with any of these vaccines. It is therefore important that the doctor carrying out the vaccination is aware that you are having or have had treatment with Rhesonativ.
- Inform your doctor that you are taking immunoglobulin when you give a blood sample, as this treatment may affect the results.

Pregnancy and breast-feeding

Rhesonativ is intended for use in pregnancy and can be used during breast-feeding.

Driving and using machines

No effects on ability to drive and use machines have been observed.

Rhesonativ contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml of solution (625 IU), that is to say essentially 'sodium-free'.

3 How to use Rhesonativ

Your doctor will decide if you need Rhesonativ and at what dose. Rhesonativ is administered as an intramuscular injection (in a muscle) by healthcare personnel.

4 Possible side effects

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

The frequency of the following side effects is not known (frequency cannot be estimated from the available data): headache, beating of the heart, low blood pressure, wheezing, vomiting, nausea, skin reactions, pain in a joint, low back pain, dizziness, fever, feelings of discomfort including chest discomfort, shivering, local reactions at the site of injection, such as swelling and pain, degradation of red blood cells and severe allergic reactions including anaphylactic shock.

If you notice any symptoms of an anaphylactic reaction like dizziness, nausea, vomiting, stomach cramps, coughing, difficulty breathing and swallowing, blueness of the skin, itching, hives, rash, beating of the heart, low blood pressure, swelling of the face, tongue or throat, collapse or pain in the chest please contact your doctor immediately because any of these conditions requires treatment immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

[*to be completed nationally]

5 How to store Rhesonativ

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the ampoule in the outer carton in order to protect from light.

Within its shelf-life, the product may be stored below 25 °C for up to 1 month, without being refrigerated again during this period, and must be discarded if not used after this.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Rhesonativ contains

- The active substance is human anti-D immunoglobulin. 1 ml contains 625 IU (125 µg) human anti-D immunoglobulin.

- One ampoule of 1 ml contains 625 IU (125 µg) of human anti-D immunoglobulin. One ampoule of 2 ml contains 1250 IU (250 µg) of human anti-D immunoglobulin.
- The human protein content is 165 mg/ml, of which immunoglobulin G is at least 95%.
- The other ingredients are glycine, sodium chloride, sodium acetate, polysorbate 80 and water for injections.

What Rhesonativ looks like and contents of the pack

Rhesonativ is a solution for injection (625 IU/ml or 1250 IU/2 ml per ampoule).

Pack sizes: 1x1 ml, 1x2 ml and 10x2 ml.

The colour of the solution can vary from colourless to pale-yellow up to light-brown.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

To be completed nationally

Manufacturer

Octapharma AB
SE-112 75 Stockholm
Sweden

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the member state	Name of the product
Austria	Rhesonativ 625 I.E./ml Injektionslösung
Bulgaria	Rhesonativ 625 IU/ml, solution for injection
Cyprus	Rhesonativ 625 IU/ml, διάλυμα για ένεση
Czech Republic	Rhesonativ 625 IU/ml, injekční roztok
Denmark	Rhesonativ, Injectionsvæske, opløsning
Estonia	Rhesonativ, 625 RÜ/ml, süstelahus
Finland	Rhesonativ 625 IU/ml injektioneste, liuos
France	Rhesonativ 625 UI/ml, solution injectable
Hungary	Rhesonativ 625 NE/ml oldatos injekció
Iceland	Rhesonativ 625 a.e./ml, stungulyf, lausn
Ireland	Rhesonativ 625 IU/ml, solution for injection
Italy	Rhesonativ 625 IU/ml Soluzione iniettabile
Latvia	Rhesonativ 625 SV/ml šķīdums injekcijām
Lithuania	Rhesonativ 625 TV/ml injekcinis tirpalas
Luxembourg	Rhesonativ 625 UI/ml, solution injectable
Malta	Rhesonativ 625 IU/ml, solution for injection
Netherlands	Rhesonativ 625 IE/ml, oplossing voor injectie
Norway	Rhesonativ 625 IE/ml injeksjonsvæske, oppløsning
Poland	Rhesonativ, 625 j.m./ml, roztwór do wstrzykiwań

Portugal	Rhesonativ 625 UI/ml, solução injetável
Romania	Rhesonativ 625 UI/ml, solutie injectabila
Slovakia	Rhesonativ 625 IU/ml injekčný roztok
Slovenia	Rhesonativ 625 i.e./ml, raztopina za injiciranje
Sweden	Rhesonativ, 625 IE/ml injektionsvätska, lösning

This leaflet was last revised in 2021-05-24.

The following information is intended for healthcare professionals only:

The product should be brought to room or body temperature before use.

Do not use solutions that are cloudy or have deposits.

The content of an opened ampoule should be used immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Injections have to be given intramuscularly and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

If intramuscular administration is contra-indicated (bleeding disorders), the injection can be administered subcutaneously if no intravenous product is available. Careful manual pressure with a compress should be applied to the site after injection.

If a large volume (>2 ml for children or >5 ml for adults) is required, it is recommended to administer this in divided doses at different sites.

This medicinal product must not be mixed with other medicinal products.

In overweight/obese patients, due to the possible lack of efficacy in case of intramuscular administration, an intravenous anti-D product is recommended.