LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Rhesonativ
(Human anti-D immunoglobulin)

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Summary Public Assessment Report

Rhesonativ

(Human anti-D immunoglobulin)

Solution for injection; 750 IU/ml

This is a summary of the public assessment report (PAR) for Rhesonativ, 750 IU/ml, solution for injection. It explains how Rhesonativ was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Rhesonativ.

For practical information about using Rhesonativ, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rhesonativ and what is it used for?

Rhesonativ is an immunoglobulin and contains antibodies to the Rhesus factor.

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.

How does Rhesonativ work?

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.

How is Rhesonativ used?

The pharmaceutical form of Rhesonativ is solution for injection. Rhesonativ is administered as an intramuscular injection (in a muscle) by healthcare personnel.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Rhesonativ have been shown in studies?

The company´s own data on efficacy and safety studies previously approved for Rhesonativ, 625 IU/ml, solution for injections is applicable for Rhesonativ, 750 IU/ml, solution for injection as well. These studies have shown that Rhesonativ is effective in treating Rh-negative women in the indications mentioned above in section *What is Rhesonativ and what is it used for?*.

What are the possible side effects of Rhesonativ?

For the full list of all side effects reported with Rhesonativ, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Rhesonativ approved?

The company´s own data on efficacy and safety studies previously approved for Rhesonativ, 625 IU/ml, solution for injections is applicable for Rhesonativ, 750 IU/ml, solution for injection as well. No new or unexpected safety concerns arose from the application.

Therefore, the Medical Products Agency in Sweden decided that Rhesonativ's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Rhesonativ?

A risk management plan has been developed to ensure that Rhesonativ is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rhesonativ, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Rhesonativ

The marketing authorisation for Rhesonativ was granted on 2017-09-14 in Sweden.

The full PAR for Rhesonativ can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Rhesonativ, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2017-09.