Human Anti-D Immunoglobulin Solution for injection, in pre-filled syringe 1500 IE

Information on Rh-prophylaxis
Rh immunisation

Everybody is unique and so is their blood and its properties. There are four blood groups A, B, AB, and O, and these are determined by the red blood cells. There is one more important difference in the blood which is called the Rh factor; this is also found on the red blood cells. People who are Rh positive have something called a D-antigen on the surface of their red blood cells. People who are Rh negative do not have this D-antigen on the surface of their blood cells. Your blood group and Rh factor are inherited from your parents. In Europe, around 85% of all people are Rh positive and 15% are Rh negative.

First pregnancy

The Rh factor can play an important role during pregnancy and birth if a Rh negative mother is expecting a Rh positive baby. This can only happen if the baby’s father is Rh positive; but, not all babies are Rh positive because they have a Rh positive father.

During pregnancy, the placenta forms a barrier between the mother’s and the baby’s red blood cells. However, sometimes, small amounts of the baby’s blood can pass into the mother’s blood.

Why you are receiving treatment with Rhophylac® (Human Anti-D Immunoglobulin)
If any of the blood cells from a Rh positive baby passes into the bloodstream of a Rh negative woman, she can react to the D-antigen in the baby's blood as if it was a foreign body and start to produce antibodies. This is called Rh sensitisation. This is generally not a problem during the first pregnancy, but can have serious consequences during later pregnancies.

In most cases, the baby's blood cells come into contact with the mother's blood during the birth. However, this can happen at any time during the pregnancy, for example if the mother has a miscarriage or abortion, when samples of the amniotic fluid or placenta are taken, or if there is bleeding, or trauma to the pelvis. These events, which can result in the mother producing antibodies against the D-antigen, are known as potential sensitising events.

**Later pregnancies**

Generally, the first baby, who triggers this sensitisation, is not affected by any undesired events because when the antibodies start to develop it has already been born. However, if the mother becomes pregnant again and the baby is Rh positive, antibodies can pass to the baby's blood and affect the red blood cells. This is called haemolytic disease of the foetus and newborn.
If later babies are Rh positive, the reaction with antibodies is often faster and more serious.

Thanks to our Rh prophylaxis with anti-D immunoglobulin, Rh sensitisation during pregnancy and after the birth can generally be avoided.

**Rh prophylaxis with Rhophylac®**

Prophylaxis means giving a medicine to avoid and prevent something happening. Rh or anti-D prophylaxis means that a medicine is given, in your case Rhophylac®, which contains anti-D immunoglobulin to prevent you forming antibodies against Rh positive blood cells, thereby preventing the baby from developing haemolytic disease. The protective effect of anti-D immunoglobulin only lasts for a short time, and the treatment must be repeated during and after each pregnancy. Rhophylac® is normally given as an injection either into a muscle (intramuscular injection) or a vein (intravenous injection).
During the pregnancy
All pregnant women who are Rh negative and who have not been immunised (those who already have antibodies against the D-antigen in their blood) are generally recommended to have prophylactic treatment with Rhophylac. This is done by a simple injection between weeks 28 and 30 of pregnancy.

After the baby has been born
After the baby has been born, his/her blood group is tested. If the child is shown to be Rh positive, the mother will receive an injection of Rhophylac®, normally within 3 days after the baby has been born. This is postnatal prophylaxis.

Complications during pregnancy
If a potentially sensitising event occurs, such as those listed below, it may require intervention by the midwife or doctor in the Mother and Baby Unit:

1. Risk of or actual miscarriage that requires surgical intervention or occurs after week 12 of pregnancy
2. Ectopic pregnancy or surgical abortion
3. Significant vaginal bleeding after week 12 of pregnancy
4. Obstetric intervention, such as taking a sample of the placenta or amniotic fluid, or external rotation
5. Hard hit against the stomach, such as from a fall or traffic accident

If an event like vaginal bleeding occurs it is very important that you let your midwife or doctor at the Maternity Clinic know as soon as possible.
Do all Rh negative pregnant women need the prophylaxis?

There are situations when this treatment is not necessary:

- If you know definitely that you will not get pregnant again, for example after sterilisation.
- If you are pregnant and the father-to-be is definitely Rh negative. Then the expected baby will also be Rh negative.

Your doctor or Maternity Clinic can advise you.

Remember!

During your pregnancy keep in touch with your doctor or midwife who will check your blood and which Rh group you belong to. Information about which Rh group you belong to will be noted in your medical records which you hand in to the Obstetrics Department. If you become pregnant again, it is important that you let people know that you have previously been given Anti-D immunoglobulin.
Note when you received an injection of Rhophylac® and show to your doctor or midwife at check-up during the first six months after treatment and at follow-up for a new pregnancy.

Name

Personal ID number

**Treatment with Rhophylac® (Human Anti-D Immunoglobulin)**

Date

Hospital

Treated by

Date

Hospital

Treated by

This information leaflet can be ordered from CSL Behring AB. For further information, see the Patient Information Leaflet that you can get from your doctor or midwife.
Rhophylac® 1500IE (300μg) solution for intravenous or intramuscular injection, in pre-filled syringe. Human Anti-D Immunoglobulin. The solution contains special proteins that have been isolated from human plasma (i.e. the fluid in the blood). These proteins belong to the type immunoglobulins (antibodies). The active substance in Rhophylac is a special type of antibody; anti-D (Rh) immunoglobulin. Anti-D (Rh) immunoglobulin is effective against Rhesus factor type D. Rhophylac is used when you are a Rh(D) negative pregnant woman, who is carrying a Rh(D) positive baby. This medicine is also used if you are a Rh(D) negative pregnant woman and it is unknown whether your child is Rh(D) positive. Rhophylac must be administered by a doctor or other healthcare personnel. Rhophylac can trigger a hypersensitivity reaction (allergic reaction). Talk to your doctor or other healthcare personnel immediately if such reactions occur. Read the Patient Information Leaflet carefully CSL Behring AB, tel.: +46 8-544 966 70 This information is based on the Patient Information Leaflet: 2016-06-30.

This leaflet has been medically reviewed by Consultant Gunilla Ajne, Pregnancy and Delivery Unit, Karolinska University Hospital, Huddinge.