CSL Behring

Rhophylac®

Human anti-D immunoglobulin
Solution for injection in pre-filled syringe 1500 IU

Information about RhD prophylaxis

Why you are being treated with Rhophylac®
(Human anti-D immunoglobulin)

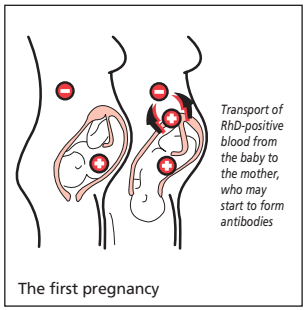
RhD immunisation

Every person is unique, and so are the properties of blood. There are four blood groups, A, B, AB and O, which are determined by the red blood cells. There is another important difference in the blood known as the RhD factor, which is also found in the red blood cells. People who are RhD-positive have something called D-antigen on the surface of their red blood cells. People who are RhD-negative do not have the D-antigen on the surface of their blood cells. The blood group and RhD factor, if present, a person has are inherited from their parents. In Europe, around 85 % of all people are RhD-positive and 15 % are RhD-negative.

The first pregnancy

The RhD factor can play an important role during pregnancy and delivery if an RhD-negative mother is expecting an RhD-positive baby. This happens only if the baby's father is RhD-positive, but not all babies who have an RhD-positive father become RhD-positive. There is a 50 % chance of a baby being RhD-negative if the father is what is known as a simple carrier of the RhD gene.

During pregnancy, the placenta forms a barrier between the red blood cells of the mother and the baby. Sometimes, however, small amounts of the baby's blood cross over into the mother's blood.



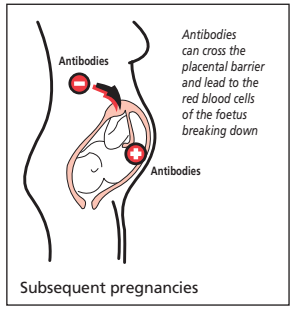
The first pregnancy

If any of the blood cells from an RhD-positive baby pass over into the blood of an RhD-negative woman, she may react to the D-antigen from the baby's blood as though it were a foreign substance and start producing antibodies. This is known as RhD immunisation. It generally does not cause a problem during the first pregnancy, but may have serious consequences during subsequent pregnancies.

The most common situation is for the baby's blood cells to come into contact with the mother's blood at the time of delivery. It may, however, happen at any time during the pregnancy, for example in miscarriage or abortion, or if something occurs during pregnancy, such as amniocentesis, chorionic biopsy, bleeding or abdominal trauma. These events, which may lead to the mother producing antibodies to the D-antigen, are known as potentially immunising events.

Subsequent pregnancies

In general, the first baby, who induces such immunisation, is not affected by any adverse events as the baby has already been born when the antibodies start to develop. If a woman becomes pregnant with a second RhD-positive baby, however, antibodies may pass over into the baby's blood and affect the baby's red blood cells. This is known as haemolytic disease of the foetus or newborn.



Subsequent pregnancies

With further RhD-positive babies, the reaction with the antibodies often becomes faster and more serious.

RhD prophylaxis with anti-D immunoglobulin enables RhD immunisation during pregnancy and after delivery to be largely avoided.

RhD prophylaxis with Rhophylac®

Prophylaxis means giving medication to prevent something from happening. RhD or anti-D prophylaxis means giving a medicine, in this case Rhophylac®, which contains anti-D immunoglobulin to prevent a woman from starting to form antibodies to RhD-positive blood cells herself and consequently to prevent the foetus from developing a haemolytic disease. The protective effect of anti-D immunoglobulin only lasts a short time, and the treatment therefore has to be repeated during and after each pregnancy. Rhophylac is given as an injection, either into a muscle (intramuscular injection) or into a vein (intravenous injection).

During pregnancy

All pregnant women who are RhD-negative, are expecting an RhD-positive baby and are not already forming antibodies to the D-antigen are generally advised to have prophylactic treatment with Rhophylac. This is given as a single injection between weeks 28 and 30 of pregnancy.

After the baby has been born

When the RhD-positive baby has been born, the woman is advised to receive an injection of Rhophylac,® usually within 3 days after the birth. This is postnatal prophylaxis.

Complications during the pregnancy

If potentially immunising events take place during the pregnancy, for example any of those listed below, RhD prophylaxis may need to be offered to you:

1. **Risk of or actual miscarriage** equiring surgery or occurring after week 12 of pregnancy
2. **Ectopic pregnancy** or surgical abortion
3. **Significant vaginal bleeding after week 12 of pregnancy,** especially if there is a simultaneous complication in the placenta
4. **Obstetric interventions** such as chorionic biopsy, amniocentesis or external version of the baby
5. **Powerful blow to the abdomen,** for example after a fall or road traffic accident

If events such as vaginal bleeding occur, it is therefore important to contact your midwife or doctor at the antenatal clinic and report this as soon as possible.

Do all RhD-negative pregnant women need prophylaxis?

There are situations in which this treatment is not needed:

- If you definitely will not become pregnant again, for example after sterilisation
- If the expected baby is RhD-negative. This can already be analysed in a blood sample from the woman in week 10 of pregnancy, and is routine in most Swedish regions

Your doctor or antenatal clinic can advise you.

Remember

During your pregnancy you will be in contact with your doctor or midwife, who will test your blood and find out what RhD group you belong to. Information about your RhD group will be documented in your medical record, which you will hand over to the maternity unit. It is important when you become pregnant to mention yourself whether you have previously received immuno-globulin anti-D.

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Treatment with Rhophylac®
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Note here

when you have received an injection of Rhophylac® and show this at check-ups with a doctor or midwife during the first six months after treatment and when you have check-ups in connection with a new pregnancy.

Name

Personal identity number

This information brochure can be ordered from CSL Behring AB. For further information, see the package leaflet which you can obtain from your doctor or midwife.

Date

Hospital

Person giving treatment

Batch no.

Date

Hospital

Person giving treatment

Batch no.

This brochure has been medically reviewed by Gunilla Ajne, Senior Physician, Pregnancy and Obstetrics, Karolinska University Hospital, Huddinge.

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