



**Rhophylac**<sup>®</sup>

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

**Information about Rhesus (Rh) prophylaxis**

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

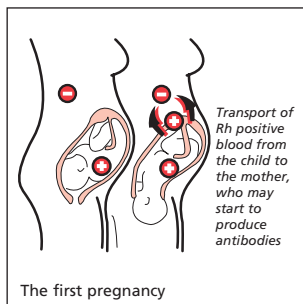
## Rh immunisation

Each person is unique, and the same applies to the properties of our blood. There are four blood groups – A, B, AB and O – and these are determined by the red blood cells. There is another important distinguishing feature in our blood called the Rhesus (Rh) factor, and this is also found in the red blood cells. People who are Rh positive have something called the D antigen on the surface of their red blood cells. Those who are Rh negative do not have the 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 people are Rh positive and around 15% are Rh negative.

## The first pregnancy

During pregnancy and childbirth, the Rh factor can play an important role if a mother who is Rh negative is expecting a child who is Rh positive. This will happen only if the child's father is Rh positive, although not all children whose father is Rh positive will be Rh positive themselves.

During pregnancy, the placenta forms a barrier between the mother's red blood cells and those of the child. Sometimes, however, small quantities of the child's blood may cross into the mother's blood.

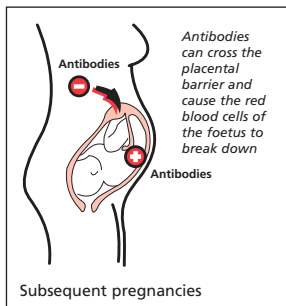


If any blood cells from a child who is Rh positive cross into the blood of a woman who is Rh negative, the woman may react to the D antigen in the child's blood as though it were a foreign substance and start to produce antibodies. This is called Rh immunisation. This is not usually a problem during the first pregnancy, but it can have serious consequences during subsequent pregnancies.

Most commonly, the child's blood cells come into contact with the mother's blood at the time of the birth. However, it can happen at any time during the pregnancy – for example, in the event of a miscarriage or abortion, or if something happens during the pregnancy, such as an amniocentesis, placenta test, bleeding or trauma to the abdomen. These events, which may cause the mother to produce antibodies to the D antigen, are termed potential immunising events.

### Subsequent pregnancies

Generally, the first child – which triggers this immunisation – is not affected by any undesirable events as it has already been born when the antibodies start to develop. However, if a woman becomes pregnant with a second Rh positive child, antibodies may pass into the child's blood and affect its red blood cells. This is called haemolytic disease of the foetus or newborn (HDFN).



With additional Rh positive children, the reaction to the antibodies often becomes more rapid and more serious.

Thanks to Rh prophylaxis with anti-D immunoglobulin, Rh immunisation during pregnancy and following childbirth can largely be prevented.

## **Rh prophylaxis with Rhophylac®**

Prophylaxis is where a drug is given in order to prevent and avoid something happening. Rh or anti-D prophylaxis involves giving a drug – in your case, Rhophylac® – containing anti-D immunoglobulin in order to prevent the woman herself from starting to produce antibodies to Rh positive blood cells, and thus preventing the foetus from developing haemolytic disease. The protective effect of anti-D immunoglobulin only lasts for a short time, and the treatment must therefore be repeated during and after every pregnancy. Rhophylac® is given as an injection, either in a muscle (intramuscular injection) or a vein (intravenous injection).

## During pregnancy

Generally, prophylactic treatment with Rhophylac® is recommended for all pregnant women who are Rh negative and who have not become immunised (already have antibodies to the D antigen in their body). This is administered as a single injection between the 28th and 30th week of pregnancy.

## After the birth of the child

When the child is born, a test is performed to determine its blood group. If the child is shown to be Rh positive, the mother is given an injection of Rhophylac®, usually within three days of the child being born. This is post-natal prophylaxis.

## Complications during pregnancy

If any potential immunising events occur – for example, any of those shown below – the midwife or doctor at the antenatal clinic may need to take action accordingly:

- 1. Risk of or actual miscarriage**  
requiring surgical intervention or occurring after the 12th week of pregnancy
- 2. Ectopic pregnancy**  
or surgical abortion
- 3. Significant vaginal bleeding after the 12th week of pregnancy**
- 4. Obstetric procedures, e.g. placenta test, amniocentesis or external turning**
- 5. Severe blow to the abdomen, e.g. after a fall or road traffic accident**

It is therefore important for you to contact and tell the midwife or doctor at your antenatal clinic as soon as possible if an event such as vaginal bleeding should occur.

## Do all pregnant women who are Rh negative require prophylaxis?

There are some situations where this treatment is not required:

- If you are certain that you will not become pregnant again, e.g. following sterilisation.
- If you are pregnant and it is certain that the father-to-be of the child is Rh negative. In that case, the child that you are expecting will also be Rh negative.

You can obtain advice from your doctor or antenatal clinic.

### Remember!

During your pregnancy, you will keep in touch with your doctor or midwife, who will – among other things – check your blood and thus which Rh group you belong to. Information on which Rh group you belong to will be documented in your patient record, which you will provide to the Maternity Clinic. If you become pregnant again, it is important that you state that you have previously been given anti-D immunoglobulin.

Make a note of when you received an injection of Rhophylac® and show them at the check-up with your doctor or midwife during the first six months following treatment, and at any checks relating to a new pregnancy.

Name

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Personal ID number

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**Treatment with Rhophylac® (Human immunoglobulin anti-D)**

Date

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Hospital

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Treatment provided by

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Date

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Hospital

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Treatment provided by

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This information leaflet can be ordered from CSL Behring AB.

For more information, please refer to the patient information leaflet, which you can obtain from your doctor or midwife.

This brochure has been medically reviewed by  
Consultant Gunilla Ajne, Pregnancy and Childbirth,  
Karolinska University Hospital, Huddinge.

**Rhophylac®** 1500 IU (300 µg) solution for intravenous or intramuscular injection in pre-filled syringe. Human anti-D immunoglobulin. The solution contains special proteins isolated from human plasma (i.e. the liquid part of blood). These proteins belong to the class of 'immunoglobulins' (antibodies). The active ingredient of Rhophylac is a specific kind of antibody called 'anti-D (Rh) immunoglobulin'. Anti-D (Rh) immunoglobulin works against Rhesus factor type D. Rhophylac is used when a pregnant woman who is Rh (D) negative is carrying a child who is Rh (D) positive. This drug is also used for pregnant women who are Rh (D) negative where it is not known whether or not the child is Rh (D) positive. Rhophylac must be administered by a doctor or other healthcare professional. Rhophylac may trigger a hypersensitivity reaction (allergic reaction). Tell your doctor or healthcare professional immediately if such reactions occur. Please read the patient information leaflet carefully. CSL Behring AB, tel. +46 8-544 966 70. This information is based on the patient information leaflet dated: 6 September 2019.

**CSL Behring**  
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