

Leflunomide Winthrop (leflunomide)

Specific Patient Information

This information sheet has been developed in accordance with the current Leflunomide Winthrop (leflunomide) Package leaflet and should be read in addition to **the** Package leaflet inserted in the medication packaging.

What should you know if you are a woman of childbearing potential, a woman with a wish to become pregnant or a man wishing to be a father?

If you are a woman of childbearing potential or a woman with a wish to become pregnant

- **Leflunomide Winthrop may increase the risk of serious birth defects**

You may be at increased risk of having a baby with a birth defect if:

- You are pregnant when you start taking Leflunomide Winthrop, or
- You become pregnant while you are taking Leflunomide Winthrop, or
- You do not wait to become pregnant until you have stopped taking Leflunomide Winthrop and followed the drug wash-out procedure described below, or
- You become pregnant within 2-years after you stopped Leflunomide Winthrop

- **Precautions of use for Leflunomide Winthrop**

If you are a woman of childbearing potential, you and your partner should take every precaution to avoid becoming pregnant, such as both partners using reliable birth control as recommended by your doctor when:

- You are currently taking Leflunomide Winthrop, or
- You have discontinued Leflunomide Winthrop and are going through the drug wash-out procedure, or
- You have discontinued Leflunomide Winthrop less than 2-years ago and have not undergone the drug wash-out procedure

It is VERY IMPORTANT that you contact your doctor IMMEDIATELY if your menstrual period is at all late or if for any other reason you believe you may be pregnant.

- **Leflunomide Winthrop wash-out procedure**

After discontinuing Leflunomide Winthrop, your doctor will order you a drug wash-out procedure.

The aim of this procedure is to remove the drug rapidly and sufficiently from your body. The wash-out procedure consists of a full 11-day course of certain drugs which speed up the removal of Leflunomide Winthrop from your body. This course is followed by 2 separate laboratory blood tests at least 14 days apart to assure a very low drug level in your body. If your Leflunomide Winthrop levels are still too high, a repeated drug wash-out procedure may be necessary.

When it is confirmed that Leflunomide Winthrop has been sufficiently removed from your body by 2 separate laboratory blood tests, you should then wait for at least another six weeks before trying to become pregnant.

If you do not follow the drug wash-out procedure, it could take up to 2 years to reach this very low drug level in your blood.

If you are a man wishing to be a father

As it can not be excluded that Leflunomide Winthrop passes into semen, reliable contraception during treatment with Leflunomide Winthrop should be guaranteed.

When you want to father a child, you should discuss with your doctor who could advise you to stop Leflunomide Winthrop and then to undergo the drug wash-out procedure (as described above).

When it is confirmed that Leflunomide Winthrop has been sufficiently removed from the body, men should wait for at least a further 3 months before attempting to father a child.

For further information, please consult your doctor.

An ad hoc advisory service is available for providing information on leflunomide plasma level testing for patients treated with Leflunomide Winthrop. Your doctor will be able to provide you with further details on request.