

# Important Patient Safety Information for Leflunomide

You have been given this information sheet because your doctor has prescribed leflunomide for you. Please read all of this information carefully in addition to the Patient Information leaflet you will find in the medicine pack.

## **What should you know if you are a woman of childbearing potential, a woman wishing to have a baby or a man wishing to be a father**

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

### **Information for women of childbearing potential and women who want to have a baby**

The unborn baby can develop serious defects if

- You take leflunomide even though you are pregnant.
- You become pregnant during treatment with leflunomide.
- You become pregnant without first having stopped treatment with leflunomide and completed the washout procedure described below.
- You become pregnant within 2 years of stopping leflunomide (without a previous washout procedure).

Precautions when using leflunomide:

- Before you start treatment make sure you are not pregnant.
- Women of childbearing potential must practice reliable contraceptive measures (both partners) while they are using leflunomide and for 2 years after they have stopped.
- If you are planning to become pregnant, please tell your doctor. You must stop taking leflunomide and you must wait for a period of 2 years or carry out the washout procedure described below to speed up the removal of leflunomide from your body.
- It is very important that you tell your doctor immediately if you think you may be pregnant (e.g. if your period starts late or any other reason) during treatment with leflunomide or within 2 years of finishing treatment.

### **Washout procedure after treatment with leflunomide**

Before you become pregnant, you must make absolutely sure that leflunomide has been almost completely removed from your body. This may take up to 2 years. This waiting period can be shortened by taking certain medicines which speed up the removal of leflunomide from your body. After taking these medicines for 11 days, two blood tests at an interval of at least 14 days must confirm that the active substance has been sufficiently removed from your body. As soon as the test shows that leflunomide is removed, you should wait for at least another month before you become pregnant.

If the blood levels are still too high, even after the washout procedure, it may be necessary to repeat the procedure.

### **Information for men**

It is possible that leflunomide passes into the seminal fluid and harms the unborn baby. Therefore, men should practice reliable contraception while they are taking leflunomide.

If you are being treated with leflunomide and plan to father a child, please contact your doctor. Your doctor can advise you to stop taking leflunomide and carry out the washout procedure described above.

## Important Patient Safety Information for Leflunomide

After that, 2 blood tests at an interval of 2 weeks must confirm that the active substance has been sufficiently removed from your body. In order to minimise the risks, you should then wait at least another 3 months before fathering a child.

If you have any questions, please contact your doctor.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, dietitian or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly via the Yellow Card Scheme at <http://www.mhra.gov.uk/yellowcard>. By reporting side effects, you can help provide more information on the safety of this medicine.

You should also report any side effects to Mylan UK Pharmacovigilance on +44 (0) 800 121 8267 and [UKPharmacovigilance@mylan.com](mailto:UKPharmacovigilance@mylan.com).

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.