

Dear Patient

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

Wanting to have a baby and pregnancy

As with most preparations in the DMARDs group (Disease Modifying Anti Rheumatic Drugs), Leflunomide medac can also harm an unborn baby.

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

The unborn baby can develop serious defects if

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

The following precautions are particularly important when using Leflunomide medac:

- Before you start treatment make sure you are not pregnant.
- Women of childbearing potential must practice reliable contraceptive measures while they are using Leflunomide medac and for 2 years after they have stopped.
- If you are planning to become pregnant please tell your doctor. You must stop taking Leflunomide medac 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 medac from your body.
- Please tell your doctor immediately if you think you may be pregnant (e.g. if your period starts late) during treatment with Leflunomide medac or within 2 years of finishing treatment.

Washout procedure after treatment with Leflunomide medac

Before you become pregnant you must make absolutely sure that Leflunomide medac 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 medac 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 medac 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 medac passes into the seminal fluid and harms the unborn baby. Therefore, men should practice reliable contraception while they are taking Leflunomide medac. If you are being treated with Leflunomide medac and plan to father a child please contact your doctor. Your doctor can advise you to stop taking Leflunomide medac and carry out the washout procedure described above. 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.