

Specific Patient Information

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

What should you know if you are a woman of childbearing potential or a woman with a wish to become pregnant:

- Leflunomide may increase the risk of serious birth defects
- -if you are pregnant when you start taking Leflunomide or
- -if you become pregnant while you are taking Leflunomide, or
- -if you do not wait to become pregnant until you have stopped taking Leflunomide and followed the drug wash-out procedure described below, or
- -if you become pregnant within 2-years after you stopped Leflunomide

Precautions of use for Leflunomide

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 or
 - You have discontinued Leflunomide and are going through the drug wash-out procedure,
- or
- You have discontinued Leflunomide less than 2-years ago

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.

Wash-out procedure

Elimination of leflunomide and its degradation products:

The Product Leflunomide Bluefish and its degradation products are expected to be in the body for prolonged period. It takes about two (2) years to eliminate leflunomide and its degradation products from the body. You shall try to accelerate the elimination of the degradation products of Leflunomide by follow your physician's instructions regarding the wash-out procedure.

During the wash-out period you may be administered colestyramine and activated powdered charcoal. These substances are known to modify the absorption of oestrogen and progestrogens, which are available in your contraceptive pills. Mini pills only contains progestogen. It is therefore important that you use alternative contraceptive methods other than oral contraceptives during the entire wash-out period. If the wash-out procedure cannot be performed, a 2-year waiting period under reliable contraception is required after treatment discontinuation before becoming pregnant.

Laboratory tests at the end of the wash-out period

Two separate laboratory tests at an interval of at least 14 days must be performed to assess the levels of leflunomide and its degradation products in your body. These laboratory test results shall be discussed with your physician before planning to become pregnant.

If you are a man wishing to be a father

As it cannot be excluded that Leflunomide Bluefish passes into semen, reliable contraception should be used during treatment with Leflunomide Bluefish.

If you are male and wish to father a child you should contact your physician. Your physician may advise you to stop taking Leflunomide Bluefish and take certain medicines to remove Leflunomide Bluefish and its degradation products rapidly and sufficiently from your body. You need to take a blood test to make sure that Leflunomide Bluefish has been sufficiently removed from your body.

You should wait for at least another three (3) months before attempting to father a child.

For further information, please contact your doctor.