

LEFLUNOMIDE NORMON 10mg/20mg

FILM-COATED TABLETS GSP

LEFLUNOMIDE

Information for the patient

This information sheet has been prepared in accordance with the current package leaflet for Leflunomide and should be read together with it. The package leaflet can be found inside the medicine package.

What should you know if you are a woman of childbearing age, who wants to become pregnant, or a man who wants to be a father?

If you are a woman of childbearing age or who wants to become pregnant, you should know the following:

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

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

- You are pregnant when you start taking Leflunomide or
- You become pregnant while taking Leflunomide or
- You become pregnant within two years after the end of Leflunomide treatment without having undergone the procedure for removing the medicinal product from the body (drug washout procedure).

- **Precautions for use of Leflunomide**

If you are a woman of childbearing age, you and your partner should take every precaution to avoid becoming pregnant. In order to do this, and on the advice of your doctor, you both need to use a reliable method of contraception. Please do not forget that you should avoid getting pregnant:

- While you are taking Leflunomide or
- If you have stopped taking Leflunomide and are following the drug washout procedure or
- If you have stopped taking Leflunomide less than 2 years ago.

It is **VERY IMPORTANT** that you contact your doctor **IMMEDIATELY** if you experience any delays in your menstrual cycle or if, for any other reason, you think you may be pregnant during treatment with Leflunomide or within two years after treatment.

- **Leflunomide washout procedure**

After stopping treatment with Leflunomide your doctor may, if necessary, prescribe a drug washout procedure. The aim of this procedure is to remove the drug from your body quickly and to sufficiently lower concentrations. The washout procedure consists of a full 11-day cycle during which you will have to take certain medicines that speed up the elimination of Leflunomide from your body. After completing this cycle and in order to confirm that the drug concentration in your body is very low, you need to do 2 blood tests separated by at least 14 days. If your Leflunomide concentrations are still too high, it may be necessary to repeat the drug washout procedure.

When these 2 blood tests confirm that Leflunomide has been sufficiently cleared from your body, you should wait at least another month before becoming pregnant.

If the drug washout procedure is not followed, it could take up to 2 years to achieve such low blood concentrations of the drug.

If you are a man who wants to be a father, you should know that:

Since it cannot be excluded that Leflunomide passes into the sperm, you should use an effective method of contraception to prevent your partner from becoming pregnant during the time you are taking this medicine.

When you wish to have a child, you should inform your doctor, who may recommend that you stop taking Leflunomide and follow the drug washout procedure (as described above).

When it is confirmed that Leflunomide has been sufficiently cleared from your body, you should wait a minimum of three months before fertilisation takes place.

For further information, please contact your doctor.

If you get any side effects, talk to your doctor or pharmacist, even in the case of side effects not listed in the medicine leaflet. In the event of a suspected adverse event, please report it to:

Mint Health Ltd, 3/4 Cantrija Complex, Triq it-Targa, Il-Maghtab, Naxxar NXR6613 Malta

Tel: +356 2093 9800

Email: pharmacovigilancemt@mint.com.mt.

Alternatively, suspected adverse reactions should be reported to:

ADR Reporting Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

Email: postlicensing.medicinesauthority@gov.mt

Website: www.medicinesauthority.gov.mt/adrportal

Date of approval of document by the Malta Medicines Authority: 22/04/2024