



DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Date: March 2021

Leflunomide: Important safety updates

Dear Healthcare professional,

The MAH in agreement with Egyptian Pharmaceutical Vigilance Center (EPVC) would like to inform you of important contraindications, strengthened warnings & Drug-Drug Interactions

As the leaflets available in the packs of Leflunomide tablets are currently undergoing important safety updates, we would like to inform you with these important safety updates till its implementation in packs.

Summary of safety updates:

A) Contraindications:

- Patient SHOULD NOT take Leflunomide if he/she is allergic to teriflunomide (used to treat multiple sclerosis)

B) Precautions & Special Warnings:

- The patient should inform his doctor before taking Leflunomide in the following cases:
- If the Patient has ever suffered from inflammation of the lung (interstitial lung disease).
- If the Patient has ever had tuberculosis or if the patient has been in close contact with someone who has or has had tuberculosis. The Patient's doctor may perform tests to see if the patient has tuberculosis.
- If the Patient is due to have specific blood test (calcium level). Falsely low levels of calcium can be detected.
- DRESS which may be caused by Leflunomide appears initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- Patient should inform the doctor if he/she has unexplained chronic diarrhea; doctor may perform additional tests for differential diagnosis.



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- The Patient should inform the doctor or pharmacist if he/she is taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription. This is especially important if patient is taking:
 - Warfarin and other oral medicines used to thin the blood, as monitoring is necessary to reduce the risk of side effects of this medicine
 - Teriflunomide for multiple sclerosis Repaglinide, pioglitazone, nateglinide, or rosiglitazone for diabetes
 - Daunorubicin, doxorubicin, paclitaxel, or topotecan for cancer
 - Duloxetine for depression, urinary incontinence or in kidney disease in diabetics
 - Alosetron for the management of severe diarrhoea
 - Theophylline for asthma
 - Tizanidine, a muscle relaxant
 - Oral contraceptives (containing ethinylestradiol and levonorgestrel)
 - Cefaclor, benzylpenicillin (penicillin G), ciprofloxacin for infections
 - Indomethacin, ketoprofen for pain or inflammation
 - Furosemide for heart disease (diuretic, water pill)
 - Zidovudine for HIV infection
 - Rosuvastatin, simvastatin, atorvastatin, pravastatin for hypercholesterolemia (high cholesterol)
 - Sulfasalazine for inflammatory bowel disease or rheumatoid arthritis
 - A medicine called colestyramine (used to reduce high cholesterol) or activated charcoal as these medicines can reduce the amount of leflunomide which is absorbed by the body."

C) Very rare side effects (may affect up to 1 in 10,000 people):

Pulmonary hypertension

Further information on the safety concern and the recommendations:

Indications:

Leflunomide is indicated for treatment of adult patients with:

- Active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD),
- Active psoriatic arthritis.



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- In addition & In order to raise the awareness of these important safety updates, this letter is currently being distributed till the packs containing updated information (Summary of Product Characteristics in English language and Patient Leaflet in Arabic language) are made available in the market.

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions according to the National Regulations.

Please continue to report suspected adverse drug reactions (ADRs) to:

The Egyptian Pharmaceutical Vigilance Center (EPVC)

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt.

PO Box: 11451

Telephone: (+2) 0225354100, Extension: 1409

Email: pv.followup@edaegypt.gov.eg

Online reporting: <http://www.eda.mohp.gov.eg>