

## Safety Alert

Sep 2024

### Leflunomide – warning about impaired wound healing after surgery

EDA performs label update to include the following:

#### Special warnings and precautions for use

##### Skin reactions

Impaired wound-healing after surgery can occur in patients during therapy with leflunomide. Based on an individual assessment, it may be considered to interrupt leflunomide treatment in the peri-surgical period and administer a washout procedure as described below. In case of interruption, the decision to resume leflunomide should be based on clinical judgment of adequate wound healing.

#### Background:

##### Therapeutic Indication

Leflunomide is indicated for the treatment of adult patients with:

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

##### Posology and method of administration

- In rheumatoid arthritis: leflunomide therapy is usually started with a loading dose of 100 mg once daily for 3 days. Omission of the loading dose may decrease the risk of adverse events

The recommended maintenance dose is leflunomide 10 mg to 20 mg once daily depending on the severity (activity) of the disease.

- In psoriatic arthritis: leflunomide therapy is started with a loading dose of 100 mg once daily for 3 days.

The recommended maintenance dose is leflunomide 20 mg once daily

#### References:

EMA ([Click here](#))