

Safety Alert

March. 2026

leflunomide – risk of pulmonary nodule

EDA performs label update to include the following:

Special warning and precautions

Respiratory reactions

Interstitial lung disease, as well as rare cases of pulmonary hypertension and pulmonary nodules have been reported during treatment with leflunomide.

Undesirable effects

Not known : pulmonary nodule

Background:

A pulmonary nodule is a small, round growth in the lung, typically less than 3 cm in diameter. They are very common and are often discovered by accident during a chest X-ray or CT scan.

Key Characteristics

- Benign (Non-cancerous): Over 90% of small nodules are harmless, often caused by old infections (scars), inflammation, or benign growths like hamartomas.
- Malignant (Cancerous): A small percentage may be early-stage lung cancer or spread from other organs.
- Size Matters: Nodules under 6 mm are very low risk; those over 20 mm (2 cm) require more immediate investigation.

Management strategy

Medical protocol usually follows a "Watchful Waiting" approach:

- Serial CT Scans: Monitoring the nodule at set intervals (e.g., 6, 12, and 24 months). If it doesn't grow in 2 years, it is officially considered benign.
- Advanced Imaging (PET Scan): Used for larger or growing nodules to check for high metabolic activity (how fast the cells "eat" sugar).
- Biopsy/Resection: Only performed if the risk of malignancy is high based on growth or appearance.

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.

Reference

EMA ([click Here](#))

