

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MELOX FORT Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 15 mg of Meloxicam.

Excipient(s): Lactose anhydrous 54.35 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Light yellow colored, one face crossly notched, round tablets.

The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Short-term symptomatic treatment of exacerbations of osteoarthritis.
- Long-term symptomatic treatment of rheumatoid arthritis or ankylosing spondylitis.
- MELOX tablet is indicated for adults and children aged 16 years and over.

4.2 Posology and method of administration

Oral use

-The total daily amount should be taken as a single dose, with water or another liquid, during a meal.

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4). The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis.

- Exacerbations of osteoarthritis: 7.5 mg/day (half a 15 mg tablet).

If necessary, in the absence of improvement, the dose may be increased to 15 mg/day (one 15 mg tablet).

- Rheumatoid arthritis, ankylosing spondylitis: 15 mg/day (one 15 mg tablet).

(See also section 'Special populations' below)

According to the therapeutic response, the dose may be reduced to 7.5 mg/day (half a 15 mg tablet).

DO NOT EXCEED THE DOSE OF 15 MG/DAY.

Special populations

Elderly (see section 5.2):

The recommended dose for long term treatment of rheumatoid arthritis and ankylosing spondylitis in elderly patients is 7.5 mg per day. (See also section 4.2 "Patients with increased risks for adverse reactions (and see section 4.4).

Patients with increased risks for adverse reactions (see section 4.4)

In patients at increased risks for adverse reactions, for example with a history of gastrointestinal pathologies or risk factors for cardiovascular pathologies, treatment should be started at a dosage of 7.5 mg per day.

