Oksamen

Oksamen – L freeze-dried for injection 20 mg, 1 vial + 1 diluent ampoule
Oksamen film-coated tablet 20 mg, 10 film-coated tablet

COMPOSITION: Each film-coated tablet contains 20 mg tenoxicam.
Each freeze-dried injection contains 20 mg tenoxicam.

PHARMACOLOGICAL PROPERTIES: Has antiinflammatory, analgesic, antipyretic and anti-rheumatic activity.

INDICATIONS:
Rheumatoid arthritis
Osteoarthritis
Ankylosing spondylitis
Arthrosis
Non-articular conditions such as tendinitis, bursitis, periartthritis of the shoulder or hips, sprains and strains
Painful, inflammatory and degenerative diseases of the musculoskeletal system such as epicondylitis, sciatica, lumbago, acute gout and traumatic cases

CONTRAINDICATIONS: Is contraindicated in patients who are hypersensitive to tenoxicam and also in patients who have a history of gastric or duodenal ulcer, gastrointestinal bleeding and chronic gastritis. Should not be administered in patients with severe renal failure or hepatic insufficiency.

WARNINGS AND PRECAUTIONS: Warnings and precautions required for all non-steroidal antiinflammatory drugs are also valid for OKSAMEN tablet and OKSAMEN-L for injection.

SIDE EFFECTS / ADVERSE EFFECTS: In prolonged clinical trials with tenoxicam (1 year) the drug was well tolerated when given in the recommended dosage. Side effects that may be seen with OKSAMEN-L for injection and OKSAMEN tablet are listed below: Gastrointestinal tract, Central nervous system, Skin and soft tissue, Urinary tract, Liver and biliary tract.

DRUG INTERACTIONS: Tenoxicam, at therapeutic doses, has no pharmacokinetic interaction with antacids, cimetidine, oral antidiabetics and oral anticoagulant agents; however, it can increase the effects of anticoagulant agents such as coumarine.

DOSEAGE AND ADMINISTRATION: The recommended dose for OKSAMEN tablet is 20 mg once daily. In prolonged therapies, maintenance dose is 10 mg daily. The recommended dose for OKSAMEN-L for injection is 20 mg once daily. In the treatment of acute gout arthritis, OKSAMEN-L for injection or OKSAMEN tablet is administered 40 mg daily for the first 2 days and 20 mg daily for the following 5 days.

STORAGE CONDITIONS: Should be kept out of reach of children, at room temperature (< 25 ºC) and in its package.

AVAILABLE FORMS: OKSAMEN tablet 20 mg, in 10-tablet blister packs
OKSAMEN-L freeze-dried for injection 20 mg, 1 vial + 1 diluent ampoule (2 mL)

NAME AND ADDRESS OF THE AUTHORISATION HOLDER: Mustafa Nevzat Ilaç Sanayii A.Ş.
Prof. Dr. Bülent Tarcan Sok., Pak İş Merkezi No: 5/1 34349 Gayrettepe/Istanbul.