FLEXEN®
KETOPROFEN

COMPOSITION - Soft gelatine capsule. Each soft gelatine capsule contains: ketoprofen 50 mg; excipients q.s.
Suppository. Each suppository contains ketoprofen 100mg; excipients q.s.
Gel. 100 g of gel contain: ketoprofen 2,5 g; excipients q.s.
Ampoule: each ampoule contains: ketoprofen 100mg; excipients q.s.
Solvent ampoule i.m.: benzylic acid, water for injection.
Solvent ampoule i.v.: water for injection.
INDICATIONS - Capsules, gel, suppositories: rheumatic, inflammatory and painful affections of various origin: osteoarthrosis of various locations; ankylosing spondilitis, acute gout, rheumatoid arthritis and periarthritis; bursitis, tendinitis, tendosynovitis, synovitis capsulitis; ischialgia, radiculitis, myalgia; contusions, sprains, dislocations and strain muscles; phlebitis, superficial thrombophlebitis, lymphangitis.
Ampoules: symptomatic treatment of the acute painful episodes during inflammatory affections of the muskuloskeletal system.
DOSAGE - **Capsules**: 2 capsules 2-3 times daily, preferably after main meals. **Suppositories:** 1-2 suppositories daily. **Gel:** 2-3 applications daily, in the affected area. **Ampoules i.v.:** 1 ampoule daily. **Ampoules i.m.:** 1 to 2 ampoules daily.
Note: The solution for i.m. injection should be employed immediately and not injected intravenously.
The injections should be performed by adopting rigorous rules of sterilisation, asepsis and antisepsis.
In the treatment of elderly patients, the dosage should be carefully established by the physician who should assess any dose reduction.
CONTRA-INDICATIONS - Active peptic ulcer, positive anamnesis of recurring peptic ulcer, chronic dyspepsia, gastritis; renal insufficiency, during intensive diuretic therapy. Leukocytopenia, piastrinopenia, serious hemocoagulation disorders; in subjects with active hemorrhages and/or hemorrhagic diathesis; during treatments with anticoagulant agents. The parenteral use should be excluded when the following conditions are present in the patient: heart failure, cirrhosis of the liver, severe hepatitis, states of renal low perfusion, advanced age. Hypersensitivity to ketoprofen. Cross hypersensitivity with acetylsalicilic acid or other anti-inflammatory drugs can exist. Thus ketoprofen should not be administered to patients in whom acetylsalicylic acid or other non-steroidal anti-inflammatory drugs have induced symptoms of asthma, rhinitis, urticaria. Due to interaction with the metabolism of arachidonic acid, the drug could cause in asthmatic patients and in predisposed subject's crisis of bronchospasm and shock and other allergic phenomena.
The administration of Ketoprofen is not advisable during pregnancy, breast-feeding (see proper paragraph) and in early childhood.
Suppositories must not be administered to patients with hemorrhoid disturbances or who have recently suffered from proctitis.
UNDESIDERABLE EFFECTS - As for the other non-steroidal anti-inflammatory drugs, normally transitory disorders in the gastroenteric tract can be encountered, such as gastralgia, nausea and vomiting, diarrhea and flatulences. In particular the use of the suppositories can cause local disorders (burning, tenesmus) and decrease of consistency of the faeces. Gastrointestinal haemotthagies, transitory dysuria, asthenia, cephalea, dizziness and cutaneous exanthema, have been reported in exceptional cases.
The use of gel can cause allergic cutaneous reactions, dermatitis, eczema, photosensibilization reactions, urticaria.
PRECAUTIONS - In patients with compromised kidney function the administration of ketoprofen must be performed with particular caution, because of the renal elimination of the drug.
Ampoules: this drug cannot be considered as a simple analgesic agent and should be employed under a close medical monitoring. Moreover, when the acute painful episode has subsided, it is prudent to pass to the employ of preparations for non-parenteral use, which, though offering qualitatively the same side-effects, are less prone to cause severe reactions. Any employ of the drug for a longer period is allowed only in the hospitals and clinics.
INTERACTIONS - Since the ketoprofen protein-bond is high, any dose of anticoagulants, diphenylhydantoin or sulfa drugs to be administered at the same time may have to be reduced.
PREGNANCY AND LACTATION - The use of the drug near delivery causes its delay. Moreover, the drug could cause, if administered during this period, alterations of the hemodynamics of the fetal pulmonary circle, with severe consequences for its respiration. Therefore, the use of the drug is not advisable during pregnancy and lactation and in infancy. There are no data about secretion in human milk therefore Ketoprofen is not recommended for use in nursing mothers.
WARNINGS - Use of the gel especially if prolonged can cause sensitisation phenomena. If this occurs interrupt treatment and adopt appropriate therapeutic measures. To avoid hypersensitivity or photosensibilization phenomena it is advisable to refrain from any exposure to sunlight.
No known effects on vigilance (driving vehicles or operating with machinery).
OVERDOSAGE - Up-to-date there have been no reports of overdosage in man. In case of accidental or voluntary overdosage a symptomatic therapy is suggested.
STORAGE - Store at temperature not exceeding 25°C
PACKAGING - 20-24-30 soft gelatine capsules 50 mg ketoprofen. 10-12-50-100 suppositories 100 mg Ketoprofen. 30 g-50 g gel 2,5% Ketoprofen. 6-60 ampoules 100 mg ketoprofen+6-60 solvent ampoules i.m. or 6-60 solvent ampoules i.v.

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