FLURIFEN®

flurbiprofen

COMPOSITION: Each tablet contains 100 mg flurbiprofen.
PHARMACEUTICAL FORM: Film coated tablet.
CLINICAL PARTICULARS: Therapeutic indications: Acute or long-term symptomatic treatment of chronic rheumatoid diseases such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis; of soft tissue inflammation and bruising such as bursitis and tendinitis; and of dysmenorrhoea.
Posology and method of administration: The recommended daily dose is 150 mg-200 mg in divided doses. Depending on the severity of symptoms, the total daily dosage may be increased up to 300 mg doses. For menstruation pain, a dosage of 100 mg can be used at the beginning of symptoms, followed by 50 mg or 100 mg every 4-6 hours. The total maximum daily dosage is 300 mg.
Contraindications: Flurbiprofen is contraindicated in patients with hypersensitivity to flurbiprofen or to any of the other ingredients. It is contraindicated in patients who have had asthma, urticaria or other allergic reactions to aspirin or other non-steroidal anti-inflammatory drugs and who have active peptic ulcer or peptic ulcer history.
Special warnings and precautions for use: Patients who are chronically treated with non-steroidal anti-inflammatory drugs should be closely monitored considering that important gastrointestinal side effects may occur. Non-steroidal anti- inflammatory drugs (NSAIDs), including flurbiprofen should be carefully used in patients with kidney and liver function impairment or with a history of kidney and liver diseases. Flurbiprofen should be used carefully in patients with heart failure, hypertension and similar illnesses because of the possibility of liquid retention and oedema. Since flurbiprofen may prolong the bleeding period, it should be carefully used especially in patients who have the potential of abnormal bleeding. Use in geriatric patients: Although the pharmacokinetics of the drug is not significantly different in geriatric patients, flurbiprofen should be used for as short as possible and at minimum effective dose in this patient group, because the gastrointestinal side effect risk is higher in this specific patient group.
Interactions with other medicinal products: When flurbiprofen and aspirin are administered together, it is reported that serum concentrations of flurbiprofen decrease by 50%. Therefore, concomitant administration of these two drugs is not recommended. NSAIDs, including flurbiprofen, may increase the effects of oral anticoagulants, and may also increase the plasma concentrations of lithium, methotrexate and cardiac glycosides. Considering that flurbiprofen may affect the bleeding parameters as other NSAIDs, the drug should be used carefully in patients on anticoagulants. When flurbiprofen is used concomitantly with ACE inhibitors, cyclosporine and diuretics, the nephrotoxicity risk may increase. Flurbiprofen may decrease the efficiency of antihypertensives such as ACE inhibitors, betablockers and diuretics. NSAIDs may increase the activity of phenytoin and sulphonylurea group diuretics. It is not appropriate to use flurbiprofen together with any other NSAIDs, because concomitant administration of several NSAIDs increases the risk of side effects. Furthermore, please note that gastrointestinal bleeding risk will increase, when NSAIDs are used together with corticoidsteroids, alcohol, bisphosphonates and oxypentiphyline. It should not be used with alcohol (gastric mucosa irritation may increase). When the drug is taken with food, absorption rate may be reduced, but not the total amount that is not absorbed. It should not be used with the following plants which have antiaggregation activity: caper grass, chaste tree fruit, primula, feverfew, garlic, ginger, ginkgo, aesculus, green tea, ginseng, red clover; administration of these plants may increase the antiaggregation activity.
Fertility, pregnancy and lactation: Pregnancy category is C for the 1st and 2nd trimesters. If the doctor thinks that the benefit of the drug is higher than its potential risk on the foetus, the drug may be administered. Pregnancy category is D for the 3rd trimester.In cases when the drug is required for the treatment of a life threatening situation in the pregnant woman, or if any other drug cannot be used for the treatment of a serious disease or if they are not sufficient to treat such disease, then flurbiprofen is administered. Continuous administration of a NSAID during the 3rd trimester of pregnancy is associated with late labour, early closure of ductus arteriosus in the foetus and continuous pulmonary hypertension in the new born infant. Use in lactation: Administration of flurbiprofen is not recommended during lactation due to the possible side effects of prostaglandin synthesis inhibitors on new born babies.
Undesirable effects: Gastrointestinal disorders: nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis and gastrointestinal bleeding. More rarely observed side effects are gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation. Hypersensitivity: Hypersensitivity reactions were reported related to the treatment with NSAIDs: nonspecific allergic reactions and anaphylaxis; asthma, deteriorative asthma, respiratory tract reactivity leading to bronchospasm or dyspnoea; different types of rash, itching, urticaria, purpura, angioedema and more rarely, skin reactions such as bullous dermatoses (including epidermal necrolysis and erythema multiforme). Cardiovascular: Oedema is reported in relation to the NSAID treatment. Other adverse events are reported less commonly and causal relationship has not been established: Kidney: Nephrotoxicity of different forms including interstitial nephritis, nephrotic syndrome and renal failure. Liver: Liver function impairment and hepatitis. Nervous system and sense organs: Vision disorders, optic neuritis, headache, paraesthesia, depression, confusion, hallucination, tinnitus, vertigo, dizziness, fatigue, exhaustion and drowsiness. Hematological: Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and hemolytic anaemia. Dermatology : Photosensitivity (for other skin reactions, see the part 'hypersensitivity'). PLEASE CONSULT YOUR DOCTOR IN CASE OF AN UNXPECTED EFFECT.
Overdose: Overdosage of flurbiprofen causes nausea, vomiting and gastrointestinal irritation. There is no specific antidote for flurbiprofen. If required, gastric lavage may be performed.
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties: Flurbiprofen is a strong non- steroidal anti-inflammatory agent. It is a phenylalkanoic acid derivative with analgesic, anti-inflammatory and antipyretic effects. It is active by the inhibition of prostaglandin biosynthesis specifically at the cyclo-oxygenase enzyme level and by inhibiting the sensitization of tissues against peripheral pain mediators.
Pharmacokinetics properties: Flurbiprofen is rapidly absorbed after oral administration, and reaches peak plasma levels in approximately 1.5 hours. Intake with food does not change the bioavailability of the drug. Synovial fluid concentrations are lower than the plasma. More than 99% is bound to serum proteins. Elimination half life is 3 to 4 hours.
It is highly metabolised, mostly in the liver. Approximately 20% is excreted in the urine as both free and conjugated form and approximately 50% as hydroxylated metabolites. The two main metabolites are (2-(2-fluoro-4'-hydroxy-4-biphenylyl)) propionic acid and (2-(2-fluoro-3'-hydroxy-4'-methoxy-4-biphenylyl) propionic acid.
PHARMACEUTICAL PARTICULARS
List of excipients: Lactose monohydrate, microcrystalline cellulose, hydroxypropyl methyl cellulose, colloidal silicon, croscarmellose sodium, magnesium stearate, titanium dioxide, PEG 4000, FD&C Blue No 2 (E132). **Shelf life:** 3 year. **Special precautions for storage:** Store below 30 °C, in the original package.
LEGAL CATEGORIES: Sold with prescription only. DO NOT USE WITHOUT CONSULTING YOUR PHYSICIAN.
MARKETING AUTHORISATION HOLDER: Dafra Pharma GmbH, Switzerland.
MANUFACTURER: BILIM PHARMACEUTICALS GOSB 41480 Gebze-Kocaeli, Turkey.

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FLURIFEN®

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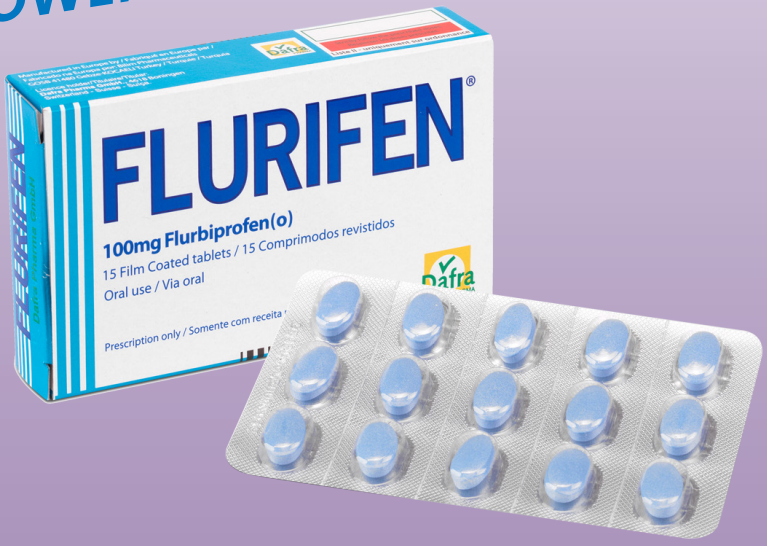
EUROPEAN GMP

Anti-inflammatory with POWERFUL AND FAST ACTION



FIRST CHOICE TREATMENT FOR:

- ✓ Dysmenorrhoea
- ✓ Acute or long-term symptomatic treatment of chronic rheumatoid diseases
- ✓ Soft tissue inflammation and bruising

Dafra PHARMA

Setting the standard

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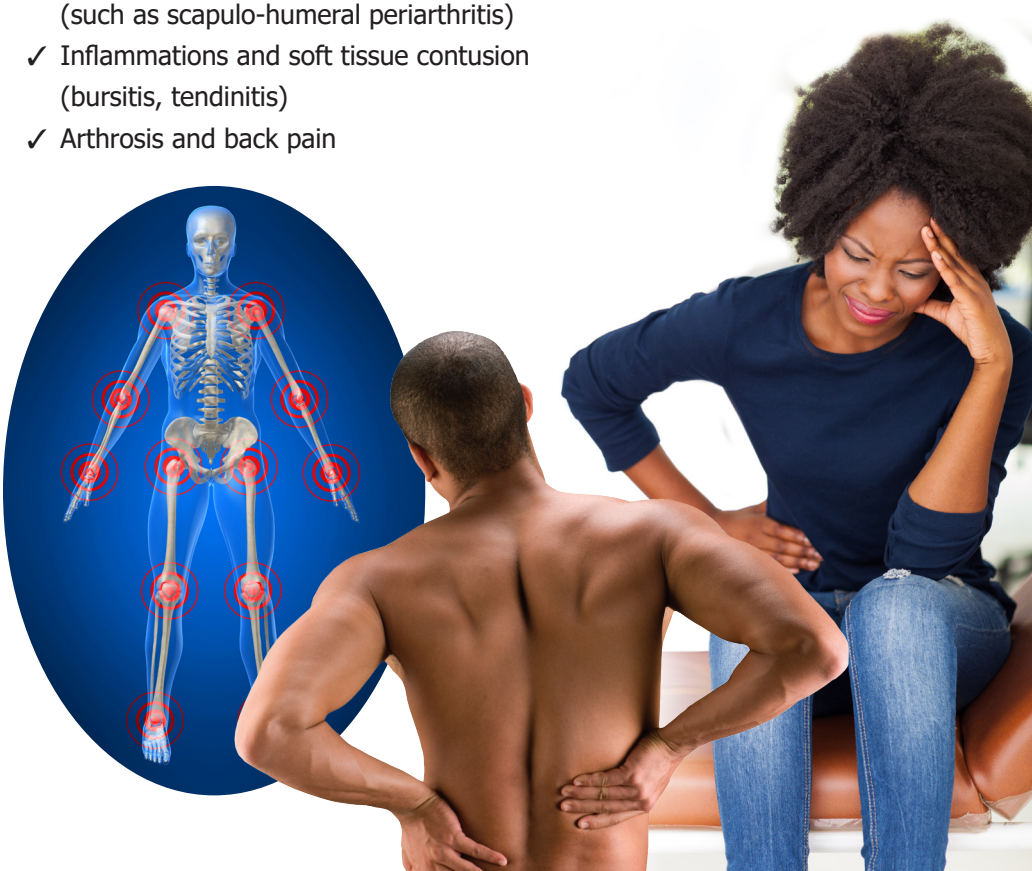
FLURIFEN®

flurbiprofen

ADULTS AND CHILDREN AS FROM 12 YEARS OLD FOR ACUTE SYMPTOMATIC OR LONG TERM TREATMENT OF

- ✓ Dysmenorrhea
- ✓ Some painful and disabling arthritis
  (Rheumatoid arthritis, ankylosing spondylitis or related syndromes)
- ✓ Chronic inflammatory rheumatism
- ✓ Abarticular rheumatism
  (such as scapulo-humeral periarthritis)
- ✓ Inflammations and soft tissue contusion
  (bursitis, tendinitis)
- ✓ Arthrosis and back pain



RECOMMENDED DAILY DOSAGE

- ✓ The recommended daily dosage is 150 mg to 200 mg in divided doses.
- ✓ Depending on the severity of symptoms, the total daily dosage may be increased to a dose of 300 mg.
- ✓ For menstrual pain, a dose of 100 mg can be used at the beginning symptoms, followed by 50 mg or 100 mg every 4-6 hours.
- ✓ The total maximum daily dose is 300 mg.

FOR EFFECTIVE AND FAST RELIEF