Dexifen®

Dexibuprofen
Tablet/ Suspension

Description

Dexifen® (Dexibuprofen) possesses analgesic and anti-inflammatory properties. Its mode of action, like that of other nonsteroidal anti-inflammatory agents, is not completely understood, but may be related to prostaglandin synthesis inhibition.

Indications

Dexifen® is indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis. Dexifen® is indicated for relief of mild to moderate pain. Dexifen® is also indicated for the treatment of primary dysmenorrhea.

Dosage and Administration

The recommended dosage is 600 to 900 mg dexibuprofen daily, divided in up to three single doses. For the treatment of mild to moderate pain, initially single doses of 200 mg and daily doses of 600 mg are recommended. The maximum single dose is 400 mg dexibuprofen. The dose may be temporarily increased up to 1200 mg dexibuprofen per day in patients with acute conditions or exacerbations. The maximum daily dose is 1200 mg. For dysmenorrhea a daily dose of 600 to 900 mg dexibuprofen, divided in up to three single doses, is recommended. The maximum single dose is 300 mg, the maximum daily dose is 900 mg.

Contraindication

Dexifen® should not be used in patients who have previously exhibited hypersensitivity to the drug, or in individuals with the syndrome of nasal polyps, angioedema, and bronchospastic reactivity to aspirin or other nonsteroidal anti-inflammatory agents.

Adverse Reactions

The most frequent type of adverse reactions occurring with Dexifen® are gastrointestinal in nature. These are dyspepsia, diarrhea, nausea, vomiting, abdominal pain, rash, fatigue or drowsiness, headache, dizziness, vertigo, peripheral edema, nephrotic syndrome. Bleeding time may be prolonged.

Precaution

Patients should be closely monitored for digestive disturbances, especially gastrointestinal bleeding, when taking dexibuprofen. As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug. In the treatment of patients with heart failure, hypertension, renal or hepatic disease, especially during concomitant diuretic treatment, the risk of fluid retention and a deterioration in renal function must be taken into account. If used in these patients, the dose of dexibuprofen should be kept as low as possible and renal function should be regularly monitored. Caution must be exercised in the treatment of elderly patients, who generally have a greater tendency to experience side effects to NSAIDs. Caution is required in patients suffering from, or with a previous history of, bronchial asthma since NSAIDs can cause bronchospasm in such patients.

Drug Interactions

Anticoagulants: The effects of anticoagulants on bleeding time can be potentiated by NSAIDs. If concomitant treatment can not be avoided blood coagulation tests (INR, bleeding time) should be performed during the initiation of dexibuprofen treatment and the dosage of the anticoagulant should be adjusted if necessary. *Methotrexate:* If NSAIDs and methotrexate are given within 24 hours of each other plasma levels of methotrexate may increase, via a reduction in its renal clearance thus increasing the potential for methotrexate toxicity. *Lithium:* NSAIDs can increase the plasma levels of lithium, by reducing its renal clearance. *Other NSAIDs and salicylates:* The concomitant use with other NSAIDs should be avoided, since simultaneous administration of different NSAIDs can increase the risk of gastrointestinal ulceration and hemorrhage. *Antihypertensives:* NSAIDs may reduce the efficacy of beta-blockers, possibly due to inhibition of the formation of vasodilatory prostaglandins. The concomitant use of NSAIDs and ACE inhibitors or angiotensin-II receptor antagonists may be associated with an increased risk of acute renal failure, especially in patients with pre-existing impairment of renal function. *Thiazides, thiazide-related substances, loop diuretics and potassium-sparing diuretics:* Concurrent use of an NSAID and a diuretic may increase the risk of renal failure secondary to a reduction in renal blood flow.

Pregnancy & Lactation

In pregnancy, no clinical data on exposed pregnancies are available. *Lactation:* Ibuprofen is slightly excreted in human milk. Breast-feeding is possible with dexibuprofen if dosage is low and the treatment period is short.

Overdose

Dexibuprofen has a low acute toxicity and patients have survived after single doses as high as 54 g of racemic ibuprofen. Most overdoses have been asymptomatic. The onset of symptoms usually occurs within 4 hours. Mild symptoms are most common, including abdominal pain, nausea, vomiting, lethargy, drowsiness, headache, nystagmus, tinnitus and ataxia. In case of ingestion of a significant amount, activated charcoal should be administered. Emptying of the stomach by emesis may only be considered if the procedure can be undertaken within 60 minutes of ingestion. Gastric lavage should not be considered unless a patient has ingested a potentially life-threatening amount of the drug and the procedure can be undertaken within 60 minutes of ingestion. Forced diuresis, hemodialysis or hemoperfusion are unlikely to be of assistance because dexibuprofen is strongly bound to plasma proteins.

Storage

Store in a cool & dry place, away from sunlight.

Commercial Pack

Dexifen® 200 Tablet: Box containing 100 tablets in 10 x 10's blister strips. Each tablet contains Dexibuprofen INN 200 mg.

Dexifen® 300 Tablet: Box containing 100 tablets in 10 x 10's blister strips. Each tablet contains Dexibuprofen INN 300 mg.

Dexifen® 400 Tablet: Box containing 100 tablets in 10 x 10's blister strips. Each tablet contains Dexibuprofen INN 400 mg.

Dexifen® Suspension : Each Bottle contains 100 ml suspension. Each 5 ml contains Dexibuprofen INN 100 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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