

Only for the use of Medical Professionals

Flamex[®]-DX

Dexibuprofen

Description

Flamex[®]-DX is a preparation of dexibuprofen which is the active enantiomer of racemic ibuprofen. Dexibuprofen is a non-steroidal anti inflammatory drug which blocks the production of prostaglandins and is therefore effective in reducing inflammation and pain.

Indications and usage

Flamex[®]-DX is indicated for-

- Pain and inflammation associated with osteoarthritis, rheumatoid arthritis & other musculoskeletal disorders
- Mild to moderate pain and inflammation including dysmenorrhoea, dental pain
- Pyrexia of unknown origin
- Headache

Dosage and administration

- The usual dose is 600 to 900 mg daily in up to 3 divided doses; increased if necessary to maximum 1200 mg daily (900 mg daily for dysmenorrhoea); maximum single dose 400 mg (300 mg for dysmenorrhoea).

Use in pregnancy and lactation

No clinical data during pregnancies is available. Ibuprofen is slightly excreted in human milk. Breast-feeding is possible with low dose and for short period of treatment.

Precautions

Dexibuprofen should be used with caution in patients with active and suspected gastrointestinal bleeding and bronchial asthma. In heart failure, hypertension, renal or hepatic disease, especially during concomitant diuretic treatment, the risk of fluid retention and deterioration in renal function should be taken into account. In case of elderly patient dexibuprofen should be started with lower dose. In case of hepatic and renal dysfunction it should be started with lower dose. It should not be used in patient with severe hepatic and renal dysfunction.

Side effects

The most common side effects are nausea, vomiting and abdominal pain. Besides these fatigue, drowsiness, headache, dizziness, vertigo, rash, peripheral odema may also occur. Bleeding time may be prolonged.

Drug interactions

Drug interactions is noticed with concomitant use of anticoagulant, methotrexate, lithium, corticosteroids, phenytoin, thiazides and thiazide related substances, other NSAIDs and salicylates, digoxin, ciclosporin, tacrolimus, beta blockers and ACE inhibitors.

Contraindications

Dexibuprofen is contraindicated in patients with known hypersensitivity to any ingredient of this preparation or individuals with acute rhinitis, nasal polyps, urticaria or angioneurotic oedema, gastrointestinal ulcer or bleeding.

Overdose

Dexibuprofen has a low acute toxicity and patients have survived after single dose as high as 54 g of racemic ibuprofen. Mild symptoms are most common including abdominal pain, nausea, vomiting, lethargy, drowsiness, headache, titinus, nystagmus and ataxia. The onset of symptoms usually occurs within 4 hours. Treatment is symptomatic and there is no specific antidote.

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Presentation

Flamex[®]-DX 200 mg tablet: White, round, film coated tablet. Each tablet contains 200 mg dexibuprofen

Flamex[®]-DX 300 mg tablet: White, oval, film coated tablet. Each tablet contains 300 mg dexibuprofen

Flamex[®]-DX 400 mg tablet: Light pink, oval, film coated tablet. Each tablet contains 400 mg dexibuprofen

Package quantities

Flamex[®]-DX 200 mg tablet: Cartons of 50 tablets in strips.

Flamex[®]-DX 300 mg tablet: Cartons of 50 tablets in strips.

Flamex[®]-DX 400 mg tablet: Cartons of 30 tablets in strips.

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