

# Dolopyx

## Ibuprofen Capsules 200 mg

### Composition :

Ibuprofen Capsules 200 mg  
Each soft gelatin capsule contains :  
Ibuprofen BP 200 mg  
Excipients Q.S.  
Approved colours used in capsules shell

### Indications:

Dolopyx is used in the management of mild to moderate pain and inflammation in conditions such as dysmenorrhoea, headache including migraine, post-operative pain, dental pain, musculoskeletal and joint disorder such as ankylosing spondylitis, osteoarthritis and rheumatoid arthritis including juvenile idiopathic arthritis, peri-articular disorders such as bursitis and tenosynovitis, and soft tissue disorders such as sprains and strains. It is also used to reduce fever. Dolopyx has also been used as an alternative to indomethacin in the treatment of patent ductus arteriosus.

### Pharmacological Properties

#### Pharmacodynamic:

Dolopyx is a nonsteroidal anti-inflammatory drug (NSAID) that possesses anti-inflammatory, analgesic and antipyretic activity. Its mode of action, like that of Other NSAIDs is not completely understood, but may be related to prostaglandin synthetase inhibition.

#### Pharmacokinetics:

After oral administration, solubilised Dolopyx (Softgel Capsules) is quickly absorbed when administered under fasting conditions. C<sub>max</sub> is achieved within 0.6 hours compared to conventional tablets (3/4 - 1 1/2 hours). When taken with food, peak levels are observed after 2 hours.

Dolopyx protein binding is approximately 99%. After an oral dose, Dolopyx is 75 - 85% excreted via kidneys during the first 24 hours (mainly in the form of two metabolites), the remainder being eliminated in the faeces following excretion in bile. Excretion is complete within 24 hours.

The half life of Dolopyx is about 2 hours.

In limited studies, Dolopyx appears in the breast milk in very low concentrations.

#### Recommended dose

The recommended dose for fever reduction in adults is 200 to 400mg every 4 to 6 hours to a maximum of 1.2g daily. Leave at least 4 hours between doses and do not take more than 1200 mg (3 capsules) in any 24 hour. Not to be used for children under 12 years of age.

#### Mode of administration

Take each dose with a full glass of water.

#### Contraindication:

- Active or previous peptic ulcer (two or more distinct episodes of proven ulceration or bleeding).
- History of upper gastrointestinal bleeding or perforation, related to previous NSAID therapy.
- Patients with severe hepatic failure, severe renal failure or severe heart failure.

#### Warnings and Precautions:

Caution (discussion with a doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Should not be used with other pain relievers such as NSAIDs.

Bronchospasms may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease and it should not be used where other NSAIDs have produced reactions.

Caution is required in patients with renal, cardiac or hepatic impairment since renal function may deteriorate. The dose should be as low as possible and renal function should be monitored.

The elderly are at increased risk of the serious consequence of adverse reactions.

Should not be given to patients who are pregnant or breastfeeding.

Caution should be taken when Dolopyx is given to patients with SLE and autoimmune diseases.

#### Interactions with other Medicaments:

Dolopyx should not be used in combination with:

Aspirin: unless low dose aspirin (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions. Other NSAIDs including cyclooxygenase-2 selective inhibitors, as these may increase the risk of adverse effects.

Dolopyx should be used with caution in combination with:

Corticosteroids: may increase the risk of adverse reactions, especially of the gastrointestinal tract, Antihypertensives and diuretics: Anticoagulants: warfarin, Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs), Cardiac glycosides, Lithium, Methotrexate, Cyclosporin, Mifepristone, Tacrolimus, Zidovudine, Quinolone antibiotics.

#### Undesirable effects

Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that use of Dolopyx, (particularly at high doses (2,400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thromboembolic events (for example myocardial infarction or stroke). Gastro-intestinal and skin disorders are most frequently reported.

Adverse effects include the following: CNS: headache, dizziness.

Gastro-intestinal: Abdominal pain, nausea and dyspepsia, constipation, diarrhoea and occasionally peptic ulcer and gastrointestinal haemorrhage, lack of appetite.

Haematological: Thrombocytopenia, occasionally agranulocytosis and aplastic anaemia. Renal: Haematuria, interstitial nephritis, renal papillary necrosis and renal failure have occasionally been reported.

Hypersensitivity reactions have been reported following treatment with Dolopyx. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

**Other:** Rarely hepatic dysfunction, hearing disturbances.

#### Overdose

In case of overdosage, headache, vomiting, drowsiness and hypotension have been reported. Hyperkalaemia may develop. Treatment is supportive with gastric lavage and correction of severe electrolyte imbalance if required.

#### Storage

Store below 30°C. Protect from light and moisture.

#### Presentation :

20 Softgel Capsules

Marketed by:



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