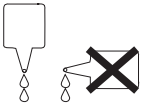
Dolphin-K 1.5 % (Oral drops)



Diclofenac Potassium

Composition:
The active ingredient is [O-[(2,6-dichlorophenyl-amino)-phenyl]-acetate resinate(= diclofenac resinate).
One hundred milliliters of Dolphin K drops contains diclofenac resinate equivalent to 1.5 g diclofenac potassium (0.5 mg per drop or 15 mg per ml).

Pharmacology :
Dolphin K drops (diclofenac potassium) has pharmacological actions similar to those of other NSAIDs. The drug exhibits antirheumatic, anti-inflammatory, analgesic, and antipyretic activity.
The exact mechanisms have not been clearly established, but many of the actions appear to be associated principally with the inhibition of prostaglandin biosynthesis.

Pharmacokinetics:

Absorption
Diclofenac is completely absorbed from the resinate suspension. The absorption sets in immediately after administration. After single administration of drops corresponding to 50 mcg diclofenac potassium, peak plasma concentrations of about 0.90 mcg / ml are attained within 1 hour.

Distribution
Diclofenac potassium extensively but reversibly bound to serum proteins, mainly albumin. At plasma diclofenac potassium concentrations of 2-10 mcg/ml, the drug is 99-99.8% protein bound in vitro.
The plasma concentrations observed in children after administration of equivalent doses are similar to those reached in adults Diclofenac potassium enters the synovial fluid and the maximum concentrations are measured 2-4 hours after peak plasma values has been obtained. The half-life of elimination from the synovial fluid is 3-6 hours . After 2 hours from reaching peak plasma concentration, the concentration of diclofenac potassium in the synovial fluid became higher than in plasma, and remain higher for up to 12 hours.

Elimination
Diclofenac potassium is excreted mainly about 60 % via kidneys as inactive metabolites, and about 39 % are excreted in the bile through the feces after glucuronidation. and about 1 % is excreted unchanged.
Half-life is about 1-2 hours.

INDICATIONS:
Dolphin K drops (diclofenac potassium) is an anti-inflammatory, anti-rheumatic, antipyretic and analgesic in different kinds of pains to be used in the following conditions:
1- Adjuvant treatment in case of painful inflammatory infections of the ear e.g. Otitis media and the throat e.g. pharingitis and tonsillitis together with the other prescribed drugs
2- Juvenile rheumatoid arthritis.
3- After teeth extraction and after tonsillectomy.
4-Painful post-operative inflammation and swelling.

Dosage:
The dosage for children aged 1 year or over should be given 0.5 - 2 mg / kg body weight daily depending on the severity of the case. The daily dose should
generally be divided in 2 - 3 doses.

Precautions:
Diclofenac potassium should be used with caution in patients with a history of GI disease or hepatic dysfunction.

Cardiovascular Risk :
NSAIDS may caus an increased risk of serious cardivascular thrombotic events, myocardial infarction, and stroke, which can be fatal,
This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk · NSAIDS is contraindicated for the treatment of peri-operative pain in the setting of coronary .artery bypass graft (CABG) surgery.

Gastrointrstinal Risk :
NSAIDS may caus an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration,and perforation of the stomach or intestines, which can be fatal. These events can occur can at any time during use and with out warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Interactions:
Concomitant use of corticosteroids during NSAIDs therapy may increase the risk of GI ulceration, therefore NSAIDs should be used with caution when concomitantly used with corticosteroids

Contraindications
- Hypersensitivity to diclofenac potassium, patients with peptic ulcer or aspirin intolerance.

Adverse reactions:
Patients may rarely suffer from gastrointestinal troubles or skin rash.

Storage conditions:
Store at temperature not exceeding 30°c

Pack: Drops 1.5 % , bottles of 15 ml.

Keep out of reach of children
To be used under medical supervision

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