

# Diclorep<sup>®</sup> Tablets (Diclofenac Potassium)

## DESCRIPTION:

**Diclorep<sup>®</sup>** chemically is diclofenac potassium is a non-steroidal anti-inflammatory drug (NSAID) taken to reduce inflammation and an analgesic reducing pain in conditions such as in arthritis or acute injury. It can also be used to reduce menstrual pain

## COMPOSITION:

Each film coated tablet contains:

Diclofenac Potassium Ph.Eur.....50mg

## CLINICAL PHARMACOLOGY:

### Pharmacodynamics

**Diclorep<sup>®</sup>** (diclofenac potassium) is a non steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and anti-pyretic properties. It inhibits prostaglandins synthesis by decreasing the activity of the enzyme, cyclo-oxygenase, which results in decreased formation of prostaglandin precursors

### PHARMACOKINETICS:

#### Absorption

Diclofenac is completely and rapidly absorbed from diclofenac potassium tablets after oral administration. The absorption sets in immediately after administration and the same amount is absorbed as from an equivalent dose of diclofenac sodium tablets. Mean peak plasma concentrations are attained after 20 - 60 minutes after ingestion of one tablet of 50mg. However due to first pass metabolism, only about 50% of the absorbed dose is systemically available. Food has no significant effect on the extent of diclofenac absorption. However, there is usually a delay in the onset and rate of absorption

#### Distribution

Diclofenac is highly bound to plasma proteins i.e. up to 99%

#### Metabolism & Excretion

Diclofenac is metabolized in liver and about 65% of the dose is excreted in urine and about 35% is excreted in the bile

## INDICATIONS:

**Diclorep<sup>®</sup>** (Diclofenac Potassium) is indicated for the treatment of signs & symptoms of rheumatoid arthritis, osteoarthritis, low back pain, active musculoskeletal disorders, such as periarthritis, tendonitis, tenosynovitis, bursitis, sprains, strains, and dislocations, relief of pain in fractures, ankylosing spondylitis, acute gout, control of pain and inflammation in orthopedic, dental and other minor surgeries. Other painful and/or inflammatory conditions like dysmenorrhoea, infections of ear, nose or throat

## CONTRAINDICATIONS:

Acute & suspected peptic ulcer or gastrointestinal bleeding. Known hypersensitivity to diclofenac or any other NSAID

## PRECAUTIONS:

### In pregnancy

Diclofenac is in the pregnancy risk category B. Diclofenac must not be taken late in pregnancy (the third trimester) because a similar drug is known to affect the baby's heart

### In nursing mothers

Diclofenac passes into breast milk, so it should be avoided

### In children

**Diclorep<sup>®</sup>** tablets are not recommended for use in children

### Others

Symptoms or history of gastrointestinal disease, asthma, impaired hepatic, cardiac or renal function. NSAIDs may mask infections or temporarily inhibit platelet aggregation. In late pregnancy, as with other NSAIDs, it should be avoided as it may cause premature closure of ductus arteriosus

## SIDE EFFECTS:

Occasional gastrointestinal disorders, headache, dizziness, vertigo, rashes, elevation of serum transaminases. Rare gastric or intestinal ulcer, gastrointestinal bleeding, abnormalities of renal function, hypersensitivity reactions

## DRUG INTERACTIONS:

### Aspirin

When Diclofenac is administered with aspirin, its protein binding is reduced. As with other

NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects

### Methotrexate, Cyclosporine

Diclofenac like other NSAIDs, through effects on renal prostaglandins, may cause increase toxicity of certain drugs. Methotrexate serum levels may be elevated as well as cyclosporine's nephrotoxicity

### Lithium

Diclofenac decreases lithium renal clearance and increases its plasma levels. In patients taking Diclofenac and lithium concomitantly, lithium toxicity may develop

### Diuretics

Diclofenac and other NSAIDs can inhibit the activity of diuretics. Concomitant treatment with potassium sparing diuretics may be associated with increased serum potassium levels

## DOSAGE AND ADMINISTRATION:

### For adults

For the relief of osteoarthritis, the recommended dosage is 100 -150mg/day in divided doses (50mg b.i.d. or t.i.d or 100mg q.d.). For the relief of rheumatoid arthritis the recommended dose is 150 - 200mg/day in divided doses (50mg t.i.d. or q.i.d. or 100mg q.d. or b.i.d.). For the relief of ankylosing spondylitis, the recommended dose is 100mg/day in divided doses

## PRESENTATION:

**Diclorep<sup>®</sup>** 50mg tablets in a pack of 20's

## STABILITY:

See expiry on the pack

## INSTRUCTIONS:

Keep out of reach of children

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine

**ڈیکلورپ ٹیبلٹ**  
(ڈیکلو فینیک پوٹاشیم)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی



Manufactured by:  
**SAMI Pharmaceuticals (Pvt.) Ltd.**  
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