

Dicloran[®] Tablets/Injection (Diclofenac Sodium)

COMPOSITION:

Dicloran[®] 50mg Tablets:
Each enteric coated tablet contains:
Diclofenac Sodium BP.....50mg

Dicloran[®] Disperlet Tablets:
Each dispersible tablet contains:
Diclofenac Acid MS
eq. to Diclofenac Sodium BP.....50mg

Dicloran[®] SR 100 Tablets:
Each sustained release tablet contains:
Diclofenac Sodium BP.....100mg

Dicloran[®] 75mg Injection:
Each 3ml contains:
Diclofenac Sodium BP.....75mg

CLINICAL PHARMACOLOGY:

Pharmacodynamics

Dicloran[®] (Diclofenac sodium) 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

Diclofenac is almost completely absorbed after oral administration. 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 of absorption of 1 to 4.5 hours. There is also a reduction in peak plasma levels. Diclofenac is approximately 99% bound to human serum proteins, primarily to albumin. Diclofenac is metabolized in liver and major portion of the dose is excreted in urine and the rest is excreted in the bile

INDICATIONS:

Dicloran[®] (Diclofenac sodium) is indicated for the treatment of signs & symptoms of rheumatoid arthritis, osteoarthritis, low back pain, active musculoskeletal disorders, such as peri-arthritis, 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 gastro-intestinal bleeding. Known hypersensitivity to diclofenac or any other NSAIDs

PRECAUTIONS:

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

SIDE EFFECTS:

Occasional gastro-intestinal disorders, headaches, dizziness, vertigo, rashes, elevation of serum transaminases, local reaction after IM injection. Rare gastric or intestinal ulcer, gastro-intestinal 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 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

Clopidogrel: Increased effect / Toxicity: When used with other drugs that can cause increased bleeding risk such as heparins, warfarins, NSAIDs and other antiplatelet drugs

DOSAGE AND ADMINISTRATION:

Tablets: 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

Injection: Usually, administered 1 ampoule of 3ml once a day

OR

As directed by the physician

STABILITY:

See expiry on the pack

PRESENTATIONS:

Dicloran[®] 50mg tablets in a pack of 20's
Dicloran[®] disperlet tablets in a pack of 20's
Dicloran[®] SR 100 tablets in a pack of 30's
Dicloran[®] 75mg injection in a pack of 5's

INSTRUCTIONS:

Keep out of reach of children
Avoid exposure to heat, light, humidity and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particle(s)



Manufactured by:
SAMI Pharmaceuticals (Pvt) Ltd.
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P002186/S

ڈیکلوران
ٹیبلٹ / انجکشن
(ڈیکلو فینیک سوڈیم)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

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

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، ڈھنڈلا ہونے یا اس میں

کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

R,N-01/HA/08/16/Carton