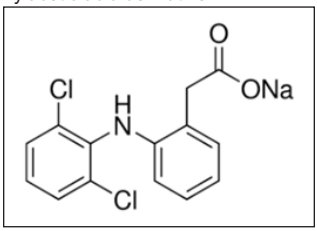
Dicloscot
Capsules*

ڈائکلوسکاٹ کیپسولز

COMPOSITION:
Each Capsule Contains: Diclofenac Sodium SR Pellets eq. to Diclofenac Sodium.....100 mg

DESCRIPTION
Diclofenac Sodium is a non-steroidal anti-inflammatory agent with analgesic as well as anti-pyretic properties. It is a phenylacetic acid derivative.



CLINICAL PHARMACOLOGY
Mechanism of Action
Exact mode of action of Diclofenac Sodium is not known. However, it inhibits the synthesis of prostaglandins, which probably play a key role in the anti-inflammatory effects of Diclofenac Sodium.
Absorption
Diclofenac is 100% absorbed after oral administration compared to IV administration as measured by urine recovery. However, due to first-pass metabolism, only about 50% of the absorbed dose is systemically available. After repeated oral administration, no accumulation of diclofenac in plasma occurred.
Distribution
The apparent volume of distribution (V/F) of diclofenac sodium is 1.4 L/kg. Diclofenac is more than 99% bound to human serum proteins, primarily to albumin. Serum protein binding is constant over the concentration range (0.15-105 mcg/mL) achieved with recommended doses. Diclofenac diffuses into and out of the synovial fluid. Diffusion into the joint occurs when plasma levels are higher than those in the synovial fluid, after which the process reverses and synovial fluid levels are higher than plasma levels. It is not known whether diffusion into the joint plays a role in the effectiveness of diclofenac.
Metabolism
Five diclofenac metabolites have been identified in human plasma and urine. The metabolites include 4' hydroxy-, 5-hydroxy-, 3'-hydroxy-, 4',5-dihydroxy- and 3'-hydroxy-4'-methoxy-diclofenac. The major diclofenac metabolite, 4'-hydroxy-diclofenac, has very weak pharmacologic activity. The formation of 4'-hydroxy diclofenac is primarily mediated by CYP2C9. Both diclofenac and its oxidative metabolites undergo glucuronidation or sulfation followed by biliary excretion.
Excretion
Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulfate conjugates of the metabolites. Little or no free unchanged diclofenac is excreted in the urine.

INDICATIONS: ***Dicloscot Capsules:*** Adults and Elderly: Relief of all grades of pain and inflammation in a wide range of conditions, including:
- Arthritic conditions: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout.
- Acute musculo-skeletal disorders, such as periarthritis (e.g., frozen shoulder), tendinitis, tenosynovitis and bursitis.
- Other painful conditions resulting from trauma, including fracture, low back pain, sprains, strains, dislocations, orthopedic, dental and other minor surgery.

Children: Not recommended.
CONTRAINDICATIONS: Hypersensitivity to Diclofenac Sodium or other non-steroidal anti-inflammatory drugs.
ADVERSE EFFECTS: Diarrhea, indigestion, nausea, constipation, flatulence, liver function test abnormalities, peptic ulcer with or without bleeding and /or perforation may occur. Abdominal pain or cramps, headache, fluid retention, abdominal distention, dizziness, rash, pruritus and tinnitus have also been reported with the use of Diclofenac Sodium.

DRUG INTERACTIONS:

Aspirin: Aspirin causes displacement of Diclofenac Sodium from its binding sites. Therefore concomitant use of aspirin and Diclofenac Sodium should be avoided.

Lithium: Diclofenac Sodium causes increased plasma levels of lithium by decreasing its renal clearance.

Oral Hypoglycemic Agents: Normally Diclofenac Sodium does not cause any change in glucose metabolism nor does it affect these agents anyway. However, rare cases have been reported about the changes in the effects of insulin and oral hypoglycemic agents. So caution is required during concomitant administration of these drugs.

Diuretics: Diclofenac may inhibit the activity of diuretics.

USE IN SPECIFIC POPULATIONS

Use in Pregnancy:

Diclofenac Sodium crosses the placental barrier in animals. No adequate studies have been carried out in pregnant females. Use of Diclofenac Sodium should be avoided during pregnancy.

Nursing Mothers:

Diclofenac Sodium is excreted in breast milk, so nursing mothers should not use it.

WARNINGS AND PRECAUTIONS: Gastrointestinal symptoms such as gastrointestinal bleeding, ulceration or even perforation can occur in the patients being treated with Diclofenac Sodium over long periods with or without any previous history of gastrointestinal symptoms. Elevation of liver function test may occur in chronic treatment with Diclofenac Sodium. Transaminases are most commonly involved so they should be periodically tested. However such elevations are reversible on withdrawal of the therapy. Therefore if abnormal liver test persists, worsen and / or clinical signs and symptoms of liver disease develop, the treatment should be discontinued. Diclofenac Sodium should not be taken empty stomach or during the state of indigestion. Fluid retention and edema have been observed in some patients taking Diclofenac, so it should be used cautiously in patients with a history of cardiac decomposition or hypertension. Few cases of renal toxicity have been reported with the use of Diclofenac Sodium. These include renal papillary necrosis and decreased renal blood flow.

DOSAGE & ADMINISTRATION:

For the relief of osteoarthritis, the recommended dosage is 1 capsule of DICLOSCOT CAPSULE100 mg once daily.

For the relief of rheumatoid arthritis, the recommended dosage is 1 capsule of DICLOSCOT CAPSULE100 mg once daily. In the rare patient where 100 mg/day is unsatisfactory, the dose may be increased to DICLOSCOT CAPSULE100 mg twice daily if the benefits outweigh the clinical risks of increased side effects.

OVERDOSE: In case of an acute overdosage, the charcoal may help to reduce the absorption of Diclofenac Sodium.

STORAGE: Store in a cool, dry and dark place between 15-30 °C. Keep all medicines out of the reach of children

PRESENTATION: Dicloscot Capsule 100 mg is available in a packing containing 30 capsules.

*Scotmann Specs.

خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: روشنی، نمی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

مستند ڈاکٹر کے نسخہ پر فروخت اور استعمال کریں۔

Complete Medical Information available only for doctors on request.

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