For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

Diclomol® EC 50

Diclofenac Tablets BP

Anti-inflammatory and Analgesic

DESCRIPTION :

Each enteric-coated tablet contains :
Diclofenac Sodium BP : 50 mg
Colour : Red Oxide of Iron and Titanium Dioxide.

Diclomol® EC 50 tablets are in a pharmaceutical formulation that resist dissolution in the low pH of gastric fluid but allows a rapid release of drug in the higher pH environment in the duodenum.

MODE OF ACTION :

Diclomol® EC 50 tablet contains diclofenac sodium, a non-steroidal, anti-inflammatory drug (NSAID). In pharmacological studies, diclofenac has shown anti-inflammatory, analgesic and antipyretic activity. As with other NSAIDs, its mode of action is not known; its ability to inhibit prostaglandin synthesis, however, may be involved in its anti-inflammatory activity, as well as contribute to its efficacy in relieving pain related to inflammation. With regards to its analgesic effect, diclofenac is not a narcotic.

In rheumatic disease, the anti-inflammatory and analgesic properties of Diclomol® EC elicit a clinical response characterised by marked relief from signs and symptoms such as pain at rest or on movement, morning stiffness and swelling of the joints, as well as by an improvement in joint function.

PHARMACOKINETICS :

Diclofenac sodium is well absorbed after oral administration and peak plasma levels are usually attained in 2-3 hours. Absorption occurs more rapidly when ingested on an empty stomach than when administered during or after a meal. Plasma concentrations show a linear relationship to the size of the dose administered. However, concentrations shown are maintained at higher levels in the synovial fluid than in plasma.

A large proportion of diclofenac sodium is metabolised in the liver and about 30% of the ingested dose undergoes first pass metabolism. Approximately 65% of the dose is excreted in the urine, and approximately 35% in the bile.

Plasma concentration of diclofenac decline from peak levels in a biexponential fashion, with the terminal phase having a half-life of approximately 2 hrs. However, the elimination half-life from the synovial fluid is about three times longer than that from plasma.

Pharmacokinetic behaviour remains unchanged following repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

No relevant age-dependent differences in the drug's absorption, metabolism, or excretion have been observed.

More than 99% is protein bound.

INDICATIONS :

Due to its anti-inflammatory and analgesic effects, Diclomol® EC is indicated for the treatment of :

- Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylosis, intervertebral disc syndrome and sciatica.
- Non-articular rheumatic conditions such as fibrositis, myositis, bursitis, low back pain, etc.
- Soft tissue injuries such as sprains, strains and sports injuries.
- Painful inflammatory conditions in gynaecology.
- Post-operative and post-traumatic inflammation and swelling.
- Pain and inflammation following dental surgery.
- Acute attacks of gout.

CONTRAINDICATIONS :

- Hypersensitivity to diclofenac sodium.
- Peptic ulcer.
- In asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetysalicylic acid or by other drugs with prostaglandin-synthetase inhibiting activity.

PRECAUTIONS :

- Close medical surveillance is required in patients with symptoms indicative of gastro-intestinal disease, a history of dyspepsia, Crohn's disease, ulcerative colitis, etc., and in patients with blood coagulation disorders, and those with severe cardiac, hepatic or renal disease.
- Caution should be exercised in elderly patients, who are generally more likely to experience side effects.
- In patients receiving long-term treatment, it is advisable to check blood counts at intervals and monitor hepatic and renal function.
- When given along with oral anticoagulants or oral antidiabetics, as a precaution the dosage of these durgs should be carefully adjusted in accordance with prothrombin time and blood glucose levels respectively.

PREGNANCY AND LACTATION :

The use of Diclomol® EC during pregnancy should, if possible, be avoided.

Diclofenac has been found in the milk of nursing mothers. As with other drugs that are excreted in milk, diclofenac is not recommended for use in nursing women.

SIDE EFFECTS :

At recommended doses, Diclomol® EC is generally well tolerated. At the start of treatment, however, patients may some times complain of epigastric pain, nausea, diarrhoea, dizziness or headache. These unwanted effects are usually of a mild nature.

The following side effects have seldom been reported with diclofenac sodium although they have been observed in response to other non-steroidal, anti-inflammatory drugs. Peripheral oedema and skin reactions, such as drug rash, urticaria and eczema. Central nervous system side effets, such as tiredness, insomnia and irritability, have occurred in rare instances. There have been a few reports of gastro-intestinal ulceration or haemorrhage, hypersensitivity reactions (e.g. bronchospasm, anaphylactoid reactions), elevated transaminase levels, hepatitis, renal failure and nephrotic syndrome, isolated cases of leucopenia and thrombocytopenia have also been observed.

DOSAGE :

As a rule the initial day dosage for adults is 1 tablet, 2 or 3 times a day. The drug should be taken with or after meals. For long-term therapy, 1 tablet, 2 times a day is sufficient.

The tablets of Diclomol® EC should neither be broken not chewed. They should be taken whole with liquid, preferably at meal times.

The recommended dosage of diclofenac sodium for childre (1 year and older) is 0.5 - 3 mg/kg/day in divided doses. Since, the Diclomol® EC tablet cannot be subdivided, it is not a suitable dosage form for children below 14 years.

HOW SUPPLIED :

Box of 100 tablets (10 strips of 10 tablets each)

STORAGE :

Store protected from light & moisture at a temperature not exceeding 30°C.

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Manufactured by :
WIN-MEDICARE PVT. LTD.
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