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

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Diclomol® Plus

Diclofenac Sodium and Paracetamol Tablets

Anti-inflammatory and Analgesic

Description

DICLOMOL® PLUS is a well tolerated combination of anti-inflammatory, analgesic and antipyretic agents. Each uncoated tablet contains Diclofenac Sodium BP 50 mg (as enteric coated granules) and Paracetamol BP 500 mg.

Mode of action & Pharmacokinetics

Diclofenac Sodium : It is a non-steroidal compound which has been demonstrated to inhibit prostaglandin biosynthesis, thus exerting a pronounced anti-inflammatory, analgesic and antipyretic action. Diclofenac sodium is well absorbed after oral administration, and peak concentrations are usually attained after 1-4 hours. Absorption occurs more rapidly when ingested on an empty stomach than when administered after a meal. Plasma concentrations show a linear relationship to the size of the dose administered, however, concentrations 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 60% of the dose is excreted through the kidney and the remainder in the faeces, in the form of metabolites. Less than 1% is excreted via the kidneys in an unchanged form.

The plasma half-life to the terminal elimination phase is about 1-2 hours. More than 99% is protein bound.

Paracetamol : The analgesic and antipyretic actions of paracetamol are similar to those of the salicylates. Analgesia is mediated peripherally and also centrally whereas antipyresis is produced by a central action on the hypothalamic regulatory centre. Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The complete ingested dose is extensively metabolised in the liver and excreted in the urine as inactive metabolites.

Both paracetamol and diclofenac sodium in DICLOMOL® PLUS tablet are well absorbed from the G.I. tract. However, paracetamol achieves peak plasma concentration much faster than diclofenac sodium, as the latter is enteric coated. This ensures rapid action and at the same time minimises the chances of gastric irritation.

Indications

Due to its anti-inflammatory and analgesic effects, DICLOMOL® PLUS is indicated for 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.
- Post-operative and post-traumatic inflammation and swelling.
- Pain and inflammation following dental surgery.
- Acute attacks of gout.

Contraindications

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

Precautions

DICLOMOL® PLUS contains diclofenac sodium and paracetamol. The precautions applicable to these two drugs also apply to the combination product as follows :

- 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 drugs should be carefully adjusted in accordance with prothrombin time and blood glucose levels respectively.

Pregnancy and Lactation

The use of DICLOMOL® PLUS during pregnancy should, if possible, be avoided.

Diclofenac sodium in oral doses of 150 mg daily passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

Adverse Effects

At recommended doses DICLOMOL® PLUS is generally well tolerated. At the start of treatment, however, patients may sometimes complain of epigastric pain, nausea, diarrhoea, dizziness or headache. These unwanted effects are usually of a mild nature. Peripheral oedema and skin reactions such as drug rash, urticaria and eczema, have also been observed.

The following side effects have seldom been reported with DICLOMOL® PLUS although they have been observed rarely : central nervous system side effects, 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

The initial daily dosage for adults is one tablet two or three times a day. The drug should be taken with or after meals. For long-term therapy, one tablet two times a day is sufficient.

Presentation

Box of 100 Tablets (10 x 10 blister strips)

Storage

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

Manufactured by :
WIN-MEDICARE PVT. LTD.
Modipuram-250 110, U.P., India.

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