CLOFEN®

Anti-inflammatory, Antirheumatic, Analgesic

Enteric-Coated Tablets, Capsules, Suppositories, Ampoules for Injection

Composition

Tablets

Each enteric-coated tablet contains:

Active ingredient: Diclofenac sodium 25mg or 50mg.

Excipients: Aerosil, lactose, cellulose, starch, povidone, magnesium stearate, hypromellose, methacrylic acid copolymer, polyethylene glycol, titanium dioxide, talc, and iron oxide yellow (and iron oxide red only in **Clofen** 50mg tablets).

CLOFEN Retard Capsules

Each capsule contains:

Active ingredient: Diclofenac sodium, in microgranules, 100mg.

Excipients: Talc, aerosil, shellac, methacrylic acid copolymer, sugar starch microgranules, and gelatin.

Suppositories

Each suppository contains:

Active ingredient: Diclofenac sodium 12.5mg, 25mg, or 100mg.

Excipients: Aerosil, hard fat, and sorbitan monostearate.

Ampoules

Each ampoule (3mL) contains:

Active ingredient: Diclofenac sodium 75mg.

Excipients: Propylene glycol, benzyl alcohol, sodium metabisulphite, sodium hydroxide, and water for injection.

Properties

CLOFEN contains a non-steroidal anti-inflammatory agent with marked antirheumatic, anti-inflammatory, analgesic, and antipyretic properties.

Diclofenac acts by inhibiting the biosynthesis of prostaglandins, which are well known to be among the mediators of inflammation, pain, and fever.

CLOFEN tablets are enteric-coated to resist gastric juices.

CLOFEN Retard capsules provide a controlled-release of the active ingredient over a long period of time so that a prolonged action is endured. They are suitable for conditions requiring 100mg diclofenac daily, especially if a long term treatment is indicated. **CLOFEN** ampoules are particularly used in preliminary treatment of inflammatory and degenerative forms of rheumatic diseases and in the treatment of nonrheumatic painful conditions.

Indications

CLOFEN is indicated for:

- Treatment of acute and chronic rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, and juvenile arthritis.
- Relief of mild to moderate pain, especially when anti-inflammatory and antipyretic effects may also be desired, e.g., following dental, obstetric, or orthopedic surgery.
- Relief of musculoskeletal and soft tissue painful and/or inflammatory conditions e.g., athletic injuries (strains or sprains), bursitis, or tendinitis.
- Relief of mild to moderate bone pain caused by metastatic neoplastic disease.
- Relief of pain and inflammation of acute attacks of gouty arthritis.
- Relief of pain and other symptoms of primary dysmenorrhea. *Note:* If acute, severe pain accompanies the above-mentioned conditions, **CLOFEN** ampoules are initially indicated to relieve such pain.
- **CLOFEN** ampoules are also effective in the quick relief of renal and biliary colics, painful post-operative inflammation and swelling, and severe migraine headache or other vascular headaches.

Dosage

The oral dosage forms should be swallowed whole; neither be fragmented nor chewed. They should be administered with a full glass of water, preferably at mealtimes to minimize gastrointestinal irritation.

- ***Adults and Children above 12 years:***

Tablets and suppositories: The usual daily dosage is 75 - 150mg in 2 - 3 fractional doses.

To suppress nocturnal pain and morning stiffness, treatment with tablets during the day can be supported by the administration of a suppository at bedtime (up to a maximum daily dose of 150mg).

In primary dysmenorrhea, the dosage is 50mg three times a day as needed. If necessary, 100mg may be administered for the first dose only.

CLOFEN Retard capsules: 1 capsule daily. If necessary, the daily dosage can be increased up to 150mg by prescribing in addition either **CLOFEN** tablets or suppositories of 25mg or 50mg. If symptoms are more severe during the night or in the morning, **CLOFEN Retard** capsules should preferably be taken in the evening.

CLOFEN ampoules: the usual dosage is 1 ampoule daily, administered by deep intramuscular injection into the upper outer quadrant of the gluteal muscle. Severe cases (e.g., colic) may require exceptionally 2 ampoules daily, with an interval of 30 minutes between injections and choosing different sites of injection. Alternatively, 1 ampoule can be combined with other dosage forms of **CLOFEN** up to a maximum daily dosage of 150mg. The ampoules should be given for a duration of 2 days only, after which treatment should be continued with **CLOFEN** tablets, capsules, or suppositories if necessary.

Migraine attacks are usually treated with **CLOFEN** suppositories.

CLOFEN ampoules should only be used for the first day of the attack.

Note: As a rule, **CLOFEN** ampoules for intramuscular injection should not be mixed with other injection solutions.

- ***Children 1 - 12 years* (for juvenile arthritis):**

Tablets and suppositories: 1 - 3mg/kg of body weight daily in 2 - 3 fractional doses.

CLOFEN Retard capsules and ampoules are not suitable for children.

If you miss a dose

If on regular dosing schedule:

- Take the missed dose as soon as possible.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications

Diclofenac is contraindicated in patients with peptic ulcer, porphyria, severe renal or hepatic impairment, or bone marrow depression, as well as allergic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or by other non-steroidal anti-inflammatory agents. Known hypersensitivity to sodium metabisulphite is a contraindication for **CLOFEN** ampoules.

Precautions

Diclofenac should be used with caution in patients with gastrointestinal disturbances, coagulation defects, or impaired cardiac, hepatic, or renal function.

The ampoule contains sodium metabisulphite as an inactive ingredient. Rarely, some susceptible patients may be hypersensitive to this substance and may develop allergic-type reactions. If any signs of hypersensitivity reactions occur, treatment should be immediately stopped, and if needed, a physician should be consulted.

Pregnancy: In general, the use of non-steroidal anti-inflammatory agents is not recommended during pregnancy, particularly the last three months, due to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.

Lactation: Diclofenac is excreted in breast milk in quantities that are considered too small to be harmful to the nursing infants.

Elderly: Elderly patients, especially those 70 years of age or older, are more likely to have an age-related renal function impairment, which may increase the risk of NSAID-induced adverse reactions; therefore, dosage reduction may be required to prevent accumulation of the drug.

Side Effects

Occasionally, diclofenac may lead to mild to moderate headache or fluid retention. Gastrointestinal disturbances including gastric pain, heartburn, nausea, constipation, or diarrhoea may be experienced. These disturbances are usually better tolerated if tablets/capsules are taken with meals. Less frequent side effects may include skin rash and itching, angioedema, photosensitivity, blood disorders, gastrointestinal ulceration, tinnitus, or dizziness.

Very rarely; irregular heartbeat, vaginal bleeding, or haematuria have been reported.

Rectal irritation may be experienced with the use of suppositories.

Overdosage

Symptoms and signs: There is no typical clinical picture resulting from an overdosage of diclofenac, however, the reported symptoms have generally reflected the gastrointestinal, renal, and CNS adverse reactions of diclofenac.

Treatment: Since there is no specific antidote, treatment of overdosage should be symptomatic and supportive. Absorption of diclofenac is usually decreased by induction of emesis (in alert patients only) or gastric lavage alongwith the administration of activated charcoal. Syrup of ipecac is usually not recommended for induction of emesis as it may induce symptoms similar to those of NSAID toxicity, thereby complicating the diagnosis.

Haemodialysis may be indicated to decrease plasma concentration of diclofenac.

Drug Interactions

The plasma concentrations of lithium, digoxin, or methotrexate may be increased upon concurrent administration with diclofenac.

Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

Side effects of diclofenac may be exacerbated when it is co-administered with other NSAIDs or corticosteroids.

Since diclofenac may inhibit platelets aggregation, patients receiving high doses or usual doses but for prolonged periods of time and taking anticoagulants concomitantly should undergo routine blood tests.

Increased risk of nephrotoxicity has been reported upon concurrent administration of cyclosporin with NSAIDs. Furthermore, cyclosporin may increase plasma concentration of diclofenac. Therefore, upon coadministration, the dose of diclofenac should be reduced to one-half of usual dose.

Presentations

CLOFEN tablets:	Pack of 20, 500, or 1000 tablets.
CLOFEN Retard capsules:	Pack of 10 or 500 capsules.
CLOFEN suppositories:	Pack of 10 suppositories of 12.5mg, 25mg, 50mg, or 100mg. Pack of 5 suppositories of 50mg or 100mg.
CLOFEN ampoules:	Pack of 5 or 50 ampoules of 3mL

** Store at a temperature of 15-25°C. Keep the tablets and the capsules in a dry place. Protect the ampoules from light and heat.*

** Store the suppositories below 30°C. Protect from heat.*

THIS IS A MEDICAMENT

- **Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor's prescription, the method of use and the instructions of the phamacist who sold the medicament.**
- **The doctor and the phamacist are experts in medicines their benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribed for you.**
- **Do not repeat the same prescription without consulting your doctor.**
- **Keep all medicaments out of reach of the children**

Council of Arab Health Ministers,
Union of Arab Phamacists

***Any information? Call Our Toll Free No.* (971) 800-4994**

julphar

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