



Composition:

Each Dio-Relax Capsule contains: Diclofenac Potassium 50 mg and Chlorzoxazone 250 mg.

Mechanism of Action:

Dio-Relax is a combination of a muscle relaxant (Chlorzoxazone) with a nonsteroidal anti-inflammatory drug (Diclofenac) that exhibits anti-inflammatory, analgesic, and antipyretic activities. The mechanism of action of Diclofenac is related to prostaglandin synthetase inhibition. While Chlorzoxazone is a centrally-acting muscle relaxant. Chlorzoxazone acts at the level of the spinal cord and subcortical regions of the brain where it inhibits the polysynaptic reflex arcs, which are involved in the production and maintenance of skeletal muscle spasm of caused by various etiologies.

Pharmacokinetics:

Diclofenac is rapidly and completely absorbed from the gastrointestinal tract, but is metabolized during the initial hepatic passage. Plasma concentrations show a linear relationship to dose size. Diclofenac is highly bound to plasma proteins (99.7%), chiefly albumin. About 60% of the administered dose is excreted in the urine as metabolites and less than 1% unchanged form.

Chlorzoxazone is rapidly absorbed from the gastrointestinal tract and peak plasma concentrations are reached approximately 1 to 2 hours after oral administration. It is rapidly metabolized and then excreted in the urine, basically as a conjugate as glucuronide. Less than 1% of a dose of Chlorzoxazone is excreted in the urine within 24 hours unchanged.

Indications:

Dio-Relax is indicated for the relief of mild to moderate pain, inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, for relief of the signs and symptoms of osteoarthritis, painful postoperative and posttraumatic inflammation, swelling and dysmenorrhoea and as an adjunct to physical therapy in the treatment of painful musculoskeletal disorders.

Contraindications:

- Hypersensitivity to the active substances or any of the excipients.
- Active gastric or intestinal ulcer, bleeding or perforation of the gastrointestinal tract.
- History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy.
- Hepatic failure and renal failure.
- Congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis.

Warnings & Precautions:

- Serious (including fatal) hepatocellular toxicity has been reported rarely in patients receiving chlorzoxazone.
- Allergic reactions including anaphylaxis have been reported with diclofenac.
- Dio-Relax should be use with in patients with hepatic problems, impaired cardiac, congestive heart failure (NYHA-I), or renal function.
- In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.
- Patients with defects of haemostasis or haematological abnormalities should be carefully monitored.

Pregnancy & Lactation:

Pregnancy: The safe use of Dio-Relax during pregnancy has not been established due to possible adverse effects on fetal development. Dio-Relax should be avoided during pregnancy because it contains diclofenac, which may cause premature closure of the ductus arteriosus in the fetus.

Lactation: Dio-Relax should not be used during lactation to avoid undesirable effects on the infant.

Drug Interactions:

- Additional CNS depression may occur in patients taking alcohol or other CNS depressants concomitantly with Chlorzoxazone.
- Diclofenac may raise plasma concentrations of lithium, phenytoin, methotrexate and digoxin.
- Diuretics and Anti-hypertensive agents (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors: concomitant use of diclofenac with diuretics or antihypertensive agents may cause a decrease in their antihypertensive effect.
- Drugs known to cause hyperkalemia: Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels.
- Anticoagulants: concomitant administration with diclofenac could increase the risk of bleeding.
- Other NSAIDs, selective serotonin reuptake inhibitors (SSRIs) and corticosteroids: Co-administration with diclofenac may increase the risk of gastrointestinal bleeding or ulceration.
- Cyclosporine: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin.
- Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
- Colestipol and cholestyramine: These agents can decrease the absorption of diclofenac.

Side Effects:

Common effects: drowsiness, dizziness, malaise, nausea, vom-

iting, diarrhoea, dyspepsia, pain and flatulence, loss of appetite, increased levels of transaminases, or overstimulation which may be occasionally observed by some patients.

Uncommon and rare effects: hypersensitivity, anaphylactic shock, gastritis, gastrointestinal bleeding, hematemesis, heart failure, palpitations, chest pain and shortness of breath.

Driving & Using Machines:

Patients who experience visual disturbances, dizziness, vertigo, somnolence while taking Dio-Relax should refrain from driving or operate machinery.

Dosage & Administration:

Usual Adult Dose: one capsule three times daily with or after meals.

Muscle Spasm: one capsule three or four times daily. The initial dosage for severe muscle spasm should be two capsules three or four times daily.

Overdose:

Symptoms:

Diclofenac: drowsiness, nausea, vomiting and epigastric pain, gastrointestinal bleeding, may also occur, but very rarely, hypertension, acute renal failure, coma.

Chlorzoxazone: Initially, gastrointestinal disturbances such as nausea or diarrhea with drowsiness, dizziness or headache may occur.

Shortly after an overdose, malaise or lethargy may occur, followed by a marked loss of muscle spasm, making voluntary movement impossible. Respiratory depression may occur with rapid and irregular breathing. Blood pressure may also drop, but shock has not been observed.

Treatment:

Gastric lavage or induction of vomiting should be performed, followed by administration of activated charcoal. After that, the treatment is completely supportive. Antacids can also reduce harmful effects on the digestive system. If respiratory function declines, use oxygen, apply artificial respiration, and secure the airway. Special measures such as induction of urination and hemodialysis may not assist in the elimination of diclofenac, due to its high protein binding and extensive subject to metabolism.

Storage:

Keep out of reach of children. Store below 30 °C.

Packaging:

Each Dio-Relax carton box contains 20 Capsules in two blister strips.

*A medication 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 pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICINES OUT OF REACH OF CHILDREN
Council of Arab Health Ministers' Union of Arab Pharmacies

