DILO®
50 mg Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DILO
DILO tablets for oral administration contain 50 mg diclofenac potassium with the following excipients: lactose monohydrate, microcrystalline cellulose, magnesium stearate, and talcum powder.
Diclofenac potassium is a non-steroidal compound with analgesic, anti-inflammatory, and antipyretic properties.
DILO tablets are indicated in the following conditions:
-Rheumatoid arthritis
-Osteoarthrosis
-Low back pain
-Migraine attacks
-Acute musculo-skeletal disorders and trauma such as periarthritis (especially frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, strains and dislocations; relief of pain in fractures
-Ankylosing spondylitis
-Acute gout
-Control of pain and inflammation in orthopedic, dental and other minor surgery
-Pyrophosphate arthropathy and associated disorders

The way to take DILO
Take DILO as directed by your physician.
Tablets should be taken with liquid, preferably before meals.
The recommended daily dose is 100-150mg (2 to 3 tablets) in two or three divided doses. For milder cases and in children over 14 years of age, 75-100 mg (one and a half to 2 tablets) daily in two or three divided doses is usually sufficient.
In migraine an initial dose of 50 mg (1 tablet) should be taken at the first signs of an impending attack. In cases where relief 2 hours after the first dose is not sufficient, a further dose of 50 mg (1 tablet) may be taken. If needed, further doses of 50 mg (1 tablet) may be taken at intervals of 4-6 hours, not exceeding a total dose of 200 mg (4 tablets) per day.

In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose
If you miss taking a dose there is no cause for concern, since analgesics may be used only when needed. However, if your health care professional has recommended that you take this drug try to remember to take it as directed.

Contraindications

This drug is contraindicated in the following conditions:
-Hypersensitivity to any of the components.
-Active, gastric or intestinal ulcer, bleeding or perforation.
-History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy.
-Active, or history of recurrent peptic ulcer/hemorrhage
-Hepatic or renal failure
-Established congestive heart failure, ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
-In patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, aspirin or other non steroidal anti-inflammatory drugs.
-Last trimester of pregnancy

Precautions

-Caution is indicated in the elderly; it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight.
-Diclofenac may mask the signs and symptoms of the infection.
-Caution should be exercised when prescribing diclofenac in patients with symptoms indicative of gastrointestinal disorders, or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation. If gastrointestinal bleeding or ulceration occurs in patients receiving diclofenac, the drug should be withdrawn.
-Caution should be exercised in patients with ulcerative colitis, or with Crohn's disease as these conditions may be exacerbated.
-Caution is indicated in patients with impaired hepatic function and in patients with hepatic porphyria. During prolonged treatment with this drug, regular monitoring of hepatic function is indicated. This drug should be discontinued if abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop.
-Caution should be exercised in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and those patients with substantial extracellular volume depletion from any cause. Monitoring of renal function is recommended in such cases.
-This drug should be discontinued at the first appearance of skin rash, mucosal lesions or any other signs of hypersensitivity.
- During prolonged treatment with this drug, monitoring of the blood count is recommended.
-The use of diclofenac is not recommended in women attempting to conceive.
-This drug should not be administered during lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
-Monitoring of the serum phenytoin, lithium, and digoxin levels is recommended when used concomitantly with diclofenac.
-Monitoring of blood glucose level is recommended when using this drug with antidiabetics.
-Use caution with diuretics, antihypertensive agents, anticoagulants, anti-platelet agents, other NSAIDs including cyclooxygenases-2 selective inhibitors, selective serotonin reuptake inhibitors,

systemic corticosteroids, methotrexate, quinolone antibiotics, cardiac glycoside, and potent CYP2C9 inhibitors.
-Serum potassium levels should be monitored when using this drug with potassium-sparing diuretics, ciclosporin, tacrolimus, and trimethoprim.
-It is recommended to administer diclofenac 4 to 6 hours after administration of colestipol/cholestyramine.
-This drug should not be used for 8-12 days after mifepristone.

Adverse reactions

The most commonly reported adverse reactions are: headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, and rash.
Rarely reported adverse reactions include: blood disorders, hypersensitivity reactions, psychiatric disorders, somnolence, tiredness, and other nervous system disorders, eye disorders, tinnitus, hearing impaired, cardiac and vascular disorders, asthma, pneumonitis.
Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

DILO, diclofenac potassium 50 mg, pack of 20 tablets

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Manufactured by Mediphar Laboratories -Lebanon