

# Divido®

## Diclofenac Sodium 75 mg Dual Release Capsules

### Composition:

Each 75 mg dual release capsule contains:  
25 mg Diclofenac Sodium in enteric-coated pellets and  
50 mg Diclofenac Sodium in sustained release pellets.  
Excipients: Talc, cellulose, povidone, silicon dioxide, propylene glycol, polymethacrylic acid derivatives, dibutyl phthalate, gelatin, coloring agents E132, E171.

### Properties:

Diclofenac Sodium is a non-steroidal anti-inflammatory drug. It is absorbed completely distally in the stomach. Orally administered Diclofenac is subject to a pronounced first pass effect. 35 - 70% of the active ingredient absorbed reaches the post hepatic circulation in unmodified condition. Approximately 30% of the active ingredient is metabolized and eliminated with the feces.

**Divido** is a hard gelatin capsule containing one part of enteric coated fast releasing pellets and a second part of sustained release pellets to combine fast and sustained release properties. Mean plasma concentrations are reached within 1 hour of oral administration.

### Indications:

- Acute joint inflammations including gout attacks.
- Chronic joint inflammations, especially chronic inflammations involving several joints (chronic polyarthritis / rheumatoid arthritis).
- Ankylosing spondylitis.
- Irritations associated with degenerative diseases of the joint and spine.
- Soft tissue rheumatism.
- Painful swellings or inflammations following injuries or operations.

### Contraindications:

**Divido** is contraindicated for patients with known hypersensitivity to any of its components and for patients with ulcers in the stomach and duodenum or porphyria.

### Precautions:

Patients with asthma, chronic obstructive airway disease, hay fever or nasal polyps react to NSAID's with asthma attack, local skin or mucous membrane swelling or urticaria more frequently than other patients, thus this medication should be given under medical supervision. Use with caution in patients with congestive heart failure, hypertension, decreased renal or hepatic function with those receiving anticoagulants.

### Interactions with other drugs:

The concurrent administration of this drug with glucocorticoids or other anti-inflammatory drugs increases the risk of gastrointestinal bleeding. The simultaneous use of acetylsalicylic acid causes a decrease in the concentration of Diclofenac in serum.

When administered concurrently, Diclofenac can increase the serum levels of digoxin, phenytoin, lithium preparations.

The concurrent administration of this drug with potassium sparing diuretics can lead to an increase in potassium levels (hyperkalemia). The co-administration of the warfarin, cyclosporin, methotrexate, sulphonylurea and insulin with the non-steroidal anti-inflammatory drugs may increase their toxicity.

### Warnings:

Since NSAID's can inhibit uterine contractions and increase the bleeding tendency, Diclofenac must not be taken in the last three months of pregnancy. The use of Diclofenac in the first 6 months of pregnancy and for lactating mothers should only be considered after a careful medical appraisal of the benefit/risk ratio.

cardiovascular risk:

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use.

patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. diclofenac is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) Surgery.

gastrointestinal risk:

NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

### Dosage and Administration:

The dosage of **Divido** depends on the severity of the illness. The recommended dose of Diclofenac Sodium for adults is between 50 and 150 mg daily.

Usually 1 capsule is taken twice daily, but in severe conditions 2 capsules can be taken in the morning daily for a short period. The capsules should be swallowed whole with sufficient amount of liquid. It is also recommended to take this medication with meals.

### Overdosage:

In case of overdose, the symptoms may include dizziness, impairment of consciousness, muscle cramps, gastrointestinal disturbances. No specific antidote is available, but you should contact your doctor immediately.

### Side Effects:

Gastrointestinal complaints such as nausea, vomiting and diarrhea are frequently expected, the risk of GI bleeding depends on the dose range and duration of use.

CNS disturbances such as headache, agitation, irritability, insomnia, tiredness, drowsiness and dizziness can occur occasionally. Hypersensitivity reactions including: rashes, angioedema and bronchospasm.

Hearing disturbances such as tinnitus, fluid retention, hepatic damage, Steven's Johnson syndrome and toxic epidermal necrosis. It should be remembered that most the side effects are dose-dependent and differ between individual patients.

Consult your Pharmacist or Physician if any side effect is observed.

### Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).

Do not use beyond the expiry date or if the product shows any signs of deterioration.

### Presentation:

Pack of 20 Capsules.

® is a trademark.

#### THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its 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 medicament out of reach of children.**

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:

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