Diclozal®

Analgesic, antirheumatic & anti-inflammatory

Composition:

- Each capsule of **DICLOZAL® S.R 100** contains:
  Diclofenac sodium BP 100 mg.
- Each Enteric coated Tablet of **DICLOZAL® 50** contains:
  Diclofenac sodium BP 50 mg.
- Each Enteric coated Tablet of **DICLOZAL® 25** contains:
  Diclofenac sodium BP 25 mg.

Indications :

DICLOZAL® is used in:-

- Inflammatory and degenerative forms of rheumatism:- rheumatoid arthritis, ankylosing spondylitis, periarthritis, osteoarthritis and spondylarthritis.
- Painful syndromes of the vertebral column.
- Non-articular rheumatism.
- Post-traumatic and postoperative pain, inflammation, and swelling.
- Painful and inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.
- Soft tissue injuries : sprain and strain.
- Dental pain, renal and biliary colics.
- Acute gout and juvenil rheumatoid arthritis.

Dosage and administration :

- The dose should be adjusted to the patient's response, tolerance and severity of symptoms.
- **DICLOZAL®** capsules or tablets should be swallowed whole with liquid preferably after meals.

Adults:

The recommended daily dosage is 75-150mg as the following:

- One capsule of **DICLOZAL® SR 100** per day.
- Or 1-3 enteric coated tablets of 25mg or 50mg/day in 2-3 divided doses.
- In primary dysmenorrhoea the daily dosage should be individually adjusted and generally 50-150mg.
- Or as directed by the physician.

Contraindications:

- Hypersensitivity to Diclofenac.
- **DICLOZAL®** should not be given to patients with peptic ulcer, gastrointestinal bleeding, and to patients who have experienced asthma, urticaria, or other allergic-type reactions caused by aspirin or other NSAIDs.

Side effects:

- **DICLOZAL®** is generally well tolerated.
- The most common side effects include gastro-intestinal disturbances, vertigo.
- Headache, and dizziness,
- Fluid retention, liver function disorders, rash and pruritis.

Precautions:

* As with other NSAIDs, **DICLOZAL®** should be used with caution in patients with:-

- Haematological abnormalities.
- Patients with impaired hepatic or renal function.
- History of cardiovascular diseases and peptic ulcer.
- The risks associated with diclofenac were particularly pronounced when taken at high doses of 150mg a day or over a long period of time.
- Patients who have serious underlying heart or circulatory conditions should not use systemic diclofenac , Furthermore , patients with certain cardiovascular risk factors (such as high blood pressure, raised blood cholesterol, diabetes or smoking) should only use diclofenac after careful consideration.

Over Dose

Symptoms include headache, nausea, vomiting, epigastric pain, GI bleeding, disorientation, drowsiness, tinnitus, coma, diarrhea and rarely convulsions.

- Patient should be treated symptomatically.
- If apotential toxic amount is ingested, activated charcoal should be considered after one hour from ingestion. Alternatively gastric lavage can be used for adults.
- In case of frequent convulsions an IV diazepam should be used.

Drug interactions:

- Like other NSAIDs, **DICLOZAL®** may reduce the efficacy of diuretics.
- Concomitant treatment with a potassium-sparing diuretic may be associated with increased serum potassium levels, which should therefore be monitored frequently.
- Patients taking **DICLOZAL®** with Digoxin, Methotrexate, Cyclosporine or lithium should be observed for potential development of the specific toxicities of these drugs.
- Concomitant administration of other systemic NSAIDs or Glucocorticoids may increase the occurrence of side effects.
- Cholestyramine appears to reduce the bioavailability of Diclofenac when the two drugs are given together; Colestipol produces a similar but smaller effect.

Pregnancy and Lactation:

- Owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus, **DICLOZAL®** should not be used in the third trimester.
- **DICLOZAL®** passes into breast milk, but in quantities so small to be harmful to a breast-fed infant.

Properties:

- Diclofenac sodium, a phenyl acetic acid derivative, is a non-steroidal compound with pronounced anti rheumatic, anti-inflammatory, analgesic and antipyretic properties.
- It inhibits prostaglandin biosynthesis which plays a major role in causing inflammation, pain and fever. Medication with Diclofenac sodium can relieve the symptoms of inflammation, but can not cure the cause. In rheumatic diseases, Diclofenac sodium elicits a clinical response characterized by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness, and swelling of the joints, as well as by an improvement in function.
- Diclofenac is almost completely absorbed. Food has no clinical relevant influence on the absorption and systemic availability of Diclofenac.
- No accumulation occurs provided the recommended dosage intervals are observed even in patients suffering from renal impairment. 99.7% of Diclofenac is bound to serum proteins. It enters the synovial fluid, and reaches higher levels in the synovial fluid than in the plasma and remain higher for up to 12 hours.
- Diclofenac is subject to first-pass metabolism and then excreted mainly in the urine (about 60%) and the reminder via the bile in metabolized form.

Packaging:

- **DICLOZAL® S.R 100 :**
  (Blister of 10 capsules, pack of one blister).
- **DICLOZAL® 50 :**
  (Blister of 10 enteric coated tablets, pack of two blisters).
- **DICLOZAL® 25 :**
  (Blister of 10 enteric coated tablets, pack of two blisters).

Storage :

- Store in a dry place below 30° C.

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 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 consultation your doctor.
- Keep medicament out of reach of children.

Produced by:
Azal Pharmaceutical Industries Co.Ltd.
Sudan - Khartoum

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حجم الخط: 6.5

رقم البانتون: 1375c

تاريخ التعديل: ٢٠١٣/٦/٢٩م

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