

# Diclogesic® (Diclofenac Sodium)

## DESCRIPTION:

**Diclogesic®** (diclofenac sodium) is a non-steroidal anti-inflammatory agent with marked anti-rheumatic, analgesic and antipyretic properties.

## PHARMACOLOGY:

Diclofenac is rapidly absorbed when given orally or as rectal suppository. It is absorbed more slowly when given as enteric coated tablet, especially when this dosage form is given with food. Although orally administered diclofenac is almost completely absorbed; it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form. At therapeutic concentrations, more than 99% of diclofenac is bound to plasma proteins. Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of glucuronide and sulfate conjugates of the metabolites. The terminal plasma half-life is about 1 to 2 hours.

## INDICATIONS:

**Diclogesic®** is used in the treatment of the following:

- Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism.
- Inflammation and swelling following dental and orthopaedic surgery.
- Acute attacks of gout.
- Post-traumatic and post-operative pain.
- Painful inflammatory conditions in gynecology and primary dysmenorrhoea.

## CONTRAINDICATIONS:

Diclofenac sodium is contraindicated in:

- Patients with known hypersensitivity to the drug.
- Patients with peptic ulcer.
- Patients who have experienced asthma, urticaria or other allergic-type reactions after taking aspirin, or other NSAIDs.

## SIDE EFFECTS:

Gastrointestinal tract: occasional epigastric pain, nausea, vomiting, diarrhea, abdominal cramps, dyspepsia, flatulence, anorexia and very rare gastrointestinal bleeding or gastric or intestinal ulcer.

Central nervous system: occasional headache, dizziness, vertigo and rare drowsiness.

Skin: occasional rashes and rare urticaria.

Kidney: rare oedema, isolated cases of acute renal failure and urinary abnormality.

Blood: isolated cases of thrombocytopenia, leucopenia, hemolytic anaemia, aplastic anaemia and agranulocytosis.

Liver: occasional elevation of serum aminotransferase enzymes and rare hepatitis.

Hypersensitivity: hypersensitivity reaction such as asthma, systemic anaphylactic/anaphylactoid reactions including hypotension.

Special senses: disturbances of vision, impaired hearing, tinnitus and taste disturbances.

## PRECAUTIONS:

- Gastrointestinal bleeding or ulceration can occur at any time during treatment with or without warning symptoms or a previous history, they generally have more serious consequences in the elderly, however, in these rare cases where gastrointestinal bleeding or ulceration occur in patients receiving **Diclogesic®** the drug should be discontinued.
- As with other NSAIDs, allergic reactions including anaphylactic/anaphylactoid reactions could also occur in rare cases without earlier exposure to the drug.
- As with other NSAIDs, values of one or more liver enzymes may increase during prolonged treatment with **Diclogesic®** monitoring of hepatic function is indicated as precautionary measure. If abnormal liver function tests persist or worsen, **Diclogesic®** should be withdrawn.
- Caution is indicated in the elderly on basic medical grounds, in particular, it is recommended that the lowest effective dosage be used in frail elderly patients or those with low body weight.
- Only **Diclogesic®** 50mg tablets contain sunset yellow, which may cause hypersensitivity reactions.
- Pregnancy: **Diclogesic®** should be employed only for compelling reasons and only in the lowest effective doses (closure of ductus arteriosus).

- Nursing mothers: The active substance passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

## DRUG INTERACTIONS:

- Aspirin: Concomitant administration of diclofenac and aspirin is not recommended because diclofenac is displaced from its binding sites during the concomitant administration with aspirin resulting in lower plasma concentrations, peak plasma levels, and AUC values.
- Digoxin, methotrexate and cyclosporin: Diclofenac, like other NSAIDs, may increase the toxicity of these drugs. Patients should be observed closely, particularly if renal function is impaired.
- Lithium: Diclofenac decreases lithium renal clearance and increases its plasma levels. In patients taking diclofenac and lithium concomitantly, lithium toxicity may develop.
- Oral Hypoglycemics: Diclofenac does not alter glucose metabolism in normal subjects nor does it alter the effects oral hypoglycemic agents. However, there are rare reports of changes in effects of insulin or oral hypoglycemic agents in the presence of diclofenac that necessitated changes in doses of such agents.
- Diuretics: Diclofenac and other NSAIDs may inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with an increase in serum potassium levels.

## DOSAGE AND ADMINISTRATION:

The recommended initial daily dosage is 100-150mg. In milder cases, as well as for long term therapy 75-100mg daily is usually sufficient. The total daily dosage should be divided into 2-3 doses. The dosage of **Diclogesic®** should be individualized to the lowest effective dose to minimize adverse effects.

- Rheumatoid arthritis: The recommended dosage is 100 - 200mg/day. In rare cases where 100mg diclofenac is unsatisfactory, the dose may be increased to 100mg twice daily. Dosage above 200mg is not recommended.
- Osteoarthritis: The recommended dosage is 100-150mg/day in 2 or 3 divided doses. More than 200mg are not recommended for patients with osteoarthritis.
- Ankylosing spondylitis: The recommended dosage is 100-125mg /day. **Diclogesic®** 25mg 4 times daily with an extra 25mg at bedtime if necessary.
- In primary dysmenorrhoea: The recommended dosage is 50mg 3 times daily. In some patients, an initial dose of 100mg followed by 50mg dose will provide better relief.
- Other indications such as post-traumatic pain, post-operative pain, dental surgery, inflammation and swelling or orthopedic surgery. The recommended dose should not exceed 150mg in 3 divided doses daily.

## OVERDOSAGE:

In the event of acute overdosage, it is recommended that the stomach be emptied by vomiting or gastric lavage. Forced Diuresis may be beneficial because the drug is excreted in the urine. The effect of dialysis or hemoperfusion in the elimination of diclofenac remains unproven. In addition to supportive measures, the use of oral activated charcoal may help to reduce the absorption of diclofenac.

## PRESENTATION:

- Diclogesic® 25** Enteric Coated Tablets: Packs of 20, 30 and 500 tablets. Each tablet contains 25mg diclofenac sodium.
  - Diclogesic® 50** Enteric Coated Tablets: Packs of 20, 30 and 500 tablets. Each tablet contains 50mg diclofenac sodium.
  - Diclogesic® Retard 100** Film Coated Tablets: Packs of 10 and 500 tablets. Each tablet contains 100mg diclofenac sodium.
  - Diclogesic® Retard 100** Capsules: Packs of 12 and 500 capsules. Each capsule contains 100mg diclofenac sodium.
  - Diclogesic® 50** Suppositories: Pack of 10 suppositories. Each suppository contains 50mg diclofenac sodium.
  - Diclogesic® 100** Suppositories: Pack of 5 suppositories. Each suppository contains 100mg diclofenac sodium.
- Diclogesic®** is also available as gel, 75mg ampoules, 12.5mg suppositories for children and eye drops.

## STORAGE CONDITIONS:

Tablets & Capsules: Protect from light. Store in a dry place below 25°C.

Suppositories: Store up to 25°C. Do not freeze.

### 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 pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and its risks.
- Do not, by yourself, interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.