DICLOMAX®

(Diclofenac sodium)

PROPERTIES

Diclomax is a Non-Steroidal Anti-Inflammatory Drug (NSAID) with antirheumatic, analgesic and antipyretic properties. Its mode of action is probably due to its ability to inhibit prostaglandin biosynthesis. Diclomax is rapidly and completely absorbed from the gastrointestinal tract with peak plasma levels occuring within 2 hours after ingestion of one 50 mg tablet and one hour after rectal administration.

INDICATIONS

Diclomax is indicated for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, painful syndromes of the vertebral column, acute gout, painful post-traumatic and post-operative inflammation and swelling (e.g. Following dental or orthopaedic surgery), primary dysmenorrhea. And in migraine attacks, Diclomax suppositories may be used.

DOSAGE AND ADMINISTRATION

Adults :

Initial daily dosage is 100-150 mg, divided into 2-3 doses. For long term therapy, or in mild cases, 75-100 mg daily divided into 2-3 doses is usually sufficient.

In primary dysmenorrhea, the dose is generally 50 -150 mg/day. It may be gradually increased, if needed, to a maximum of 200 mg/day divided into 2-3 doses. Treatment of migraine attacks with Diclomax suppositories should be initiated with a dose of 100 mg at the first signs of an impending attack. In case where pain relief is not sufficient within 4 hours after administration of the first dose, a further dose of up to 100 mg may be taken on the same day. No data are available on the treatment of migraine attacks with Diclomax for more than one day. To prevent nocturnal pain and morning stiffness, treatment with tablets during the day can be supplemented by a suppository taken at bedtime (upto a maximum daily dose of 150 mg).

Children :

Children from the age of 1 year upwards should be given 0.5-2mg/Kg body weight daily, in 2-3 divided doses depending on the severity of the condition. For the treatment of juvenile rheumatoid arthritis the daily dosage may be raised to a maximum of 3 mg/Kg body weight, given in divided doses.

CONTRAINDICATIONS

Peptic ulcer, known hypersensitivity to Diclofenac sodium. Like other NSAIDs, Diclofenac sodium is contraindicated in Asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis have been precipitated by aspirin or other NSAIDs. Diclofenac suppositories are contraindicated in proctitis.

WARNINGS

Patients experiencing dizziness or other disturbances of the CNS during treatment with Diclofenac should not drive or operate machinery.

Pregnancy/Lactation :

During 1st and 2nd trimesters, animal studies have shown no risk for the fetus, but no controlled studies in pregnant women are available (FDA Pregnancy Category B during 1st and 2nd trimesters). Diclofenac sodium should not be given during the 3rd trimester owing to the risk of premature closure of the ductus arteriosus and suppression of uterine contractility (FDA Pregnancy Category D during 3rd trimester).

Diclofenac sodium is secreted in breast milk in small quantities that no unwanted effects on the infant are likely to occur.

PRECAUTIONS

Diclofenac sodium should be used cautiously in patients with a history of gastrointestinal disease or bleeding, patients suffering from cardiovascular diseases, patients with severe hepatic or renal damage and in patients who are taking diuretics or other NSAIDs or corticosteroids. While studies have not shown Diclofenac to interact with anticoagulants of the Warfarin type, caution should be exercised. Like other NSAIDs, Diclofenac may elevate Digoxin, Methotrexate and Cyclosporine's serum levels.

SIDE EFFECTS

Diclofenac sodium is generally well tolerated. Side effects are infrequent and mild in nature such as dyspepsia, nausea, skin reactions (e.g. urticaria, rarely), minor CNS symptoms such as headache and dizziness. Elevated serum aminotransferase values (SGOT, SGPT) has occured occasionally. Thrombocytopenia and haemolytic anemia have been reported in isolated cases. Some renal disturbances also have been reported in isolated cases (e.g. haematuria, proteinuria). Rare cases of hypersensitivity reactions such as asthma may occur.

OVERDOSAGE

In case of overdose take necessary supportive measures by performing gastric lavage and giving activated charcoal.

PRESENTATION

Tablets

Diclomax 25	:	Diclofenac sodium BP 25 mg / tablet.
Diclomax 50	:	Diclofenac sodium BP 50 mg / tablet.
Diclomax Retard	:	Diclofenac sodium BP 100 mg / tablet.

Suppositories

Diclomax 12.5	:	Diclofenac sodium BP 12.5 mg / suppository.
Diclomax 50	:	Diclofenac sodium BP 50 mg / suppository.
Diclomax 100	:	Diclofenac sodium BP 100 mg / suppository.

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

Keep medicament out of the reach of children

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JPI
Jazeera Pharmaceutical Industries
P.O.Box 106229, Riyadh 11666, Saudi Arabia.