

VOTREX®

(Diclofenac sodium)

ACTION

Votrex is a non-steroidal agent with anti-rheumatic, anti-inflammatory, analgesic and anti-pyretic properties.

INDICATIONS

Votrex 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 dysmenorrhoea and as an adjuvant therapy in severe painful inflammatory infections of the ear, nose and throat, e.g. pharyngotonsillitis, otitis. Fever alone is not an indication. Votrex ampoules are also indicated in renal colic.

DOSAGE AND ADMINISTRATION

Votrex tablets (orally): The tablet should be swallowed whole with liquid, preferably before meals.

Adults

Osteoarthritis: 100-150 mg/day into 2-3 divided doses.

Rheumatoid arthritis: 150-200 mg/day in divided doses.

Ankylosing spondylitis: 100-125 mg/day into 4-5 divided doses.

In primary dysmenorrhoea: The usual daily dose is 50-150 mg, which may be gradually increased, if needed, to a maximum of 200 mg/day divided into 2-3 doses.

Other indications: Initial daily dosage is 100-150 mg, divided into 2-3 doses. Long term therapy, or in mild cases, the daily dosage is 75-100 mg divided into 2-3 doses.

Votrex retard: One tablet or capsule daily. If necessary, the daily dosage can be increased to 150 mg by supplementation with Votrex 25 or 50 mg tablets or suppositories.

Votrex suppositories (rectally): 25-100 mg suppositories can be administered as a substitute for the last oral dose of the day. In more severe cases combined therapy with Votrex 25 or 50 tablets may be used. The total daily dose should not exceed 150 mg.

Children (rectally): Children from the age of 1 year upwards should be given 0.5-2 mg/kg body weight daily divided in 2-3 doses. For the treatment of juvenile rheumatoid arthritis, the daily dosage may be raised to a maximum of 3 mg/kg body weight divided in 2-3 doses.

Votrex ampoules are given intramuscularly: 1 ampoule (75 mg) once daily or if required in severe conditions 75 mg twice daily.

Renal colic: 1 ampoule (75 mg) which may be repeated once after 30 minutes if necessary. It is possible to combine one ampoule of votrex with other forms of votrex up to a maximum of 150 mg of Diclofenac sodium. Votrex ampoules should not be given for more than 2 days. If necessary, the treatment can be continued with other dosage forms of Votrex.

CONTRAINDICATIONS

Peptic ulcer. Hypersensitivity to Diclofenac sodium. Diclofenac sodium is

contraindicated in asthmatic patients in whom acute asthmatic attacks, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs.

Diclofenac sodium suppositories are contraindicated in proctitis.

WARNINGS

Patients experiencing dizziness or other central nervous system disturbances should refrain from driving a vehicle or operating machines. Safety for the use of Diclofenac sodium during pregnancy has not yet been established.

PRECAUTIONS

Diclofenac sodium should be used cautiously in patients with a history of gastrointestinal disease or bleeding, patients with severe hepatic or renal damage, and in patients who are taking diuretics or other non steroidal anti-inflammatory drugs or corticosteroids.

SIDE EFFECTS

Diclofenac sodium is generally well tolerated. Side effects are infrequent and mild in nature such as dyspepsia, nausea, skin reactions and minor CNS symptoms.

OVERDOSAGE

In case of overdose take necessary supportive measures.

PRESENTATION

Tablets

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| VOTREX 25: | Diclofenac sodium 25 mg |
| VOTREX 50: | Diclofenac sodium 50 mg |
| VOTREX Retard: | Diclofenac sodium 100 mg |

Suppositories

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| VOTREX 12.5: | Diclofenac sodium 12.5 mg |
| VOTREX 25: | Diclofenac sodium 25 mg |
| VOTREX 50: | Diclofenac sodium 50 mg |
| VOTREX 100: | Diclofenac sodium 100 mg |

Capsules

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| VOTREX Retard: | Diclofenac sodium 100 mg |
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Ampoules

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| VOTREX IM: | Diclofenac sodium 75 mg/3 ml |
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THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, 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 the reach of children.

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