

Diclofenac 25mg/ml – 3ml Injection Ampoules

Uses

Diclofenac is a non-steroidal anti-inflammatory (NSAID) drug used to treat pain associated with conditions like gout, migraine, rheumatoid arthritis, sprains of muscles and joints and in mild to moderate fever in some cases.

Diclofenac injection is used in:

Rheumatoid Arthritis: to treat symptoms like swelling, pain, and stiffness of joints.

Osteoarthritis: to treat symptoms like tender and painful joints.

Ankylosing Spondylitis: to treat symptoms like stiffness and pain.

Dysmenorrhea: to relieve excessive pain and cramps during menstruation.

Mild to moderate pain: to relieve pain of sprains, strains, sports injuries etc.

Migraine: to relieve acute pain in migraine.

Bursitis: to relieve swelling and pain in joints caused by the inflammation of the bursae.

Tendinitis: to relieve pain and swelling associated with the tissue connecting the muscle and bones.

Dose and method of administration

Diclofenac injection should be administered by a trained healthcare professional as per the doctor's instructions.

Single dose for adults is 75 mg (one ampoule). If necessary, repeated injection is possible, but not earlier than in 12 hours. Maximum daily dose is 150 mg (2 ampoules).

Duration of intramuscular injection of the product should not exceed 2 weeks, for patients over 65 years - no more than 2 days, under close medical supervision, then shift to oral administration.

Dosage in elderly patients: Non-steroidal anti-inflammatory agents should be used cautiously in patients with increased risk of adverse reactions. The use of the lowest effective dose is recommended in fragile elderly patients or in patients with reduced body weight; it is necessary to control the development of gastrointestinal bleeding in patients upon administration of NSAIDs.

Dosage in renal insufficiency: Diclofenac is contraindicated in patients with severe renal insufficiency.

Dosage in hepatic insufficiency: Diclofenac is contraindicated in patients with severe hepatic insufficiency. It is recommended to prescribe diclofenac cautiously in patients with mild or moderate hepatic insufficiency.

Contraindications

Diclofenac injection is not recommended for use: • if you have a known history of allergy to medicines belonging to NSAIDs • if you have peptic ulcer or are suspected of having it • in erosive and ulcerative lesions of the gastrointestinal tract, gastrointestinal bleeding or perforation • in bronchial asthma, urticaria or acute rhinitis • in patients with a known history of NSAID-sensitive asthma • in severe renal/hepatic and heart insufficiency • in disorders of hematopoiesis • in patients with established ischemic heart disease, peripheral arterial diseases, or cerebrovascular diseases • in children under 15 years old • during pregnancy and lactation.

This medicine should be used with caution in patients with a history of kidney diseases due to the increased risk of severe adverse effects.

Diclofenac injection is not recommended for relieving pain after you have undergone a Coronary Artery Bypass Surgery (CABG) due to the increased risk of serious adverse effects.

Effects on ability to drive and use machines

During treatment period a patient should refrain from driving vehicles and other potentially dangerous activities that require high concentration and speed of psychomotor reactions.

Pregnancy and lactation

It is not recommended for women planning pregnancy. Women experiencing difficulties with conception and with infertility should discontinue diclofenac administration.

Suppression of prostaglandin synthesis may adversely affect the course of pregnancy and fetal development. When using prostaglandin synthesis inhibitors during the third trimester of pregnancy the fetus may have:

• premature closure of the ductus arteriosus and pulmonary hypertension;
• renal dysfunction, which progression develops in renal failure with oligohydramnios. The mother and the fetus/neonate may experience prolonged bleeding; anti-aggregation effect may occur even after administration of very low doses of diclofenac.

Lactation period: As other NSAIDs, diclofenac is excreted in breast milk in small quantities. Diclofenac is contraindicated during lactation period.

Overdose

Symptoms: dizziness, headache, pulmonary hyperventilation, mental confusion, myoclonic seizures, nausea, vomiting, abdominal pain, bleeding, compromised hepatic and renal function.

Treatment: gastric lavage, administration of activated charcoal, symptomatic therapy aimed at eliminating increased blood pressure, renal impairment, convulsions, gastrointestinal irritation, respiratory depression. Forced diuresis and hemodialysis are ineffective (due to significant protein-binding and intensive metabolism).

Missed Dose

The missed dose of Diclofenac injection should be used as soon as possible. It is advisable to skip the missed dose if it is already time for your next scheduled dose. Do not double the dose to make up for the missed one.

How to store

Store in a place protected from light and moisture at temperature below 25 °C. Keep out of reach of children. Do not use after expiration date.

This leaflet only contains a summary of the information on the medicine. The content of this leaflet should not be considered complete. It should not be used in place of a call or visit to a medical, health or other competent professional, who should be consulted before adopting any of the suggestions on this leaflet. No rights can be derived from the information provided in this instruction leaflet. Approved by pharmacist: M.H.H Janssen on 30-1-2023