

Indometacin 100mg Suppositories

Uses

Indometacin has non-steroidal analgesic and anti-inflammatory properties. It is indicated for the following conditions: • active stages of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, degenerative joint disease of the hip, acute musculoskeletal disorders, gout and lumbago • inflammation, pain and oedema following orthopedic procedures • treatment of pain and associated symptoms of primary dysmenorrhea.

Dose and method of administration

Method of Administration: For rectal administration.

Indometacin suppositories may be used when night pain and morning stiffness are prominent. One suppository at bedtime frequently gives relief from pain and stiffness for 13-16 hours after administration.

Adults: One suppository (100mg) to be inserted at night and repeated in the morning, if necessary.

Elderly: The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Children: Safety for use in children has not been established.

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.

Contraindications

• Hypersensitivity to indometacin or to any of the excipients. • Previous hypersensitivity reactions (e.g., asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs. • History of recurrent peptic ulcer/hemorrhage (two or more distinct episodes of proven ulceration or bleeding) • Severe heart failure, hepatic failure and renal failure. • History of proctitis, hemorrhoids or rectal bleeding. • History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. • Not to be used in patients with nasal polyps. • Not to be used during the last trimester of pregnancy. • Safety in children has not been established.

Special warnings and precautions for use

The use of indometacin with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Cardiovascular, Renal and Hepatic Impairment: The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients.

Cardiovascular and cerebrovascular effects: Appropriate monitoring and advice are required for patients with a history of hypertension and and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory disorders: Caution is required if administered to patients suffering from or with a previous history of bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

Undesirable side effects

Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or previous history of serious GI events. The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation.

If you experience any of the abovelisted or unlisted undesirable side effects, contact your doctor.

Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

Pregnancy and lactation

Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation after use of prostaglandin synthesis inhibitor in early pregnancy. During the first and second trimester of pregnancy, indometacin should not be given unless clearly necessary. If indometacin is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Consequently, indometacin is contraindicated during the third trimester of pregnancy.

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should be avoided when breastfeeding.

Overdose

Symptoms of overdose include: headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions, abdominal pain, anorexia, restlessness and agitation. In cases of significant poisoning acute renal failure and liver damage are possible.

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

How to store

Store at room temperature. Keep out of reach of children. Do not use this medication after the expiry date.