

Indometacin 25mg, 50mg Capsules

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

For oral administration. The dosage should be carefully adjusted according to the needs of the individual patient. In chronic conditions start the therapy with a low dosage, increasing as required.

To reduce the possibility of gastro-intestinal disturbances, indometacin capsules should always be taken with food, milk or an antacid.

Adults: The recommended oral dosage range is 50-200mg daily.

Acute rheumatoid arthritis: Initially 25mg two or three times a day.

Chronic rheumatic disorders: 25mg two or three times daily. (If response is inadequate, gradually increase by 25mg. Adequate response is usually achieved with not more than 150mg daily, rarely more than 200mg daily).

Sudden flare up of chronic condition: Increase, if necessary, by 25mg daily until a satisfactory response is obtained, or a dosage of 150-200mg daily is reached. (If this causes any adverse effects, it should be reduced to a tolerable level for two or three days, then carefully increased, as tolerated).

Acute musculoskeletal disorders: Initially 50mg two or three times daily for 10-14 days. Normally 150mg daily, rarely 200mg daily.

Lumbago: 50mg two or three times daily. Duration of treatment is not normally more than five days, but may be continued for up to 10 days.

Gout - Acute attack: 50mg three or four times daily until symptoms subside.

Following orthopedic procedures: Normally 100-150mg daily in divided doses until symptoms subside.

Additional considerations: In conditions where patients require a dosage of 150-200mg a day, it is often possible to reduce this gradually to a maintenance level of 75- 100mg a day. In patients with persistent night pain and/or morning stiffness, a dose of up to 100mg at bed time may be helpful in affording relief. It is rarely necessary to exceed a dosage of 200mg a day.

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. • NSAIDs are contraindicated in patients who have previously shown 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

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

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

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

During the first and second trimester of pregnancy, indometacin should not be given unless clearly necessary. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

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.

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

Overdose

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. 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.

How to store

Store below 25°C in a dry place. Protect from light. Keep out of reach of children. Do not use after the expiry date.