

HOVID INDOMETHACIN CAPSULE

VIMET01-M

Description

Grey and white capsule with MC 25 HD printed on both body and cap of the capsule.

Composition

Indomethacin 25 mg per capsule.

Actions and Pharmacology

Indomethacin has analgesic, anti-inflammatory and antipyretic actions. Its mode of action may involve inhibition of prostaglandin synthesis.

Pharmacokinetics

Oral absorption is rapid but is delayed by antacids. Plasma protein binding is extensive; it undergoes hepatic metabolism and both renal and faecal excretions.

Indications

For treatment of:

Rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, other rheumatic disorders and acute gout.

Contraindications

Not recommended in patients with peptic ulcer or a history of gastrointestinal lesions, or to those who are sensitive to aspirin.

Warning

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (eg. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (eg. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Precautions

- Caution in patients with impaired renal or hepatic function, and to those with bleeding disorders; epilepsy, parkinsonism, psychiatric disorders; or conditions predisposing to fluid retention such as compromised cardiac failure.
- This drug is preferably administered after meals or with food to reduce gastrointestinal irritation.
- This medication may cause drowsiness in some patients. Caution when driving or operating machinery. Avoid alcoholic beverages.
- Elderly patients may be more susceptible to the toxic effects of indomethacin.
- Safety for use has not been established in children under 14 years of age, and in pregnancy and lactation.
- Indomethacin may mask the signs of infections, the drug should be used with extra care in the presence of existing controlled infection.

Pregnancy and Lactation

Safety for use has not been established in pregnancy and lactation.

Main Side/Adverse Effects

Headache, dizziness or lightheadedness, gastrointestinal disturbances, depression, tinnitus and blurred vision with prolonged therapy, gastrointestinal ulceration and bleeding, oedema, weight gain and skin rashes.

Drug Interactions

- Co-administration of alcohol or other anti-inflammatory medications may enhance the risk of ulcerogenic effects.
- Concurrent use with aspirin or other salicylates may increase the incidence of gastrointestinal side effects without providing additional symptomatic relief.
- Caution in patients receiving the following drug therapy: Frusemide, anticoagulants, lithium, probenecid.

Overdosage

Clinical features: Nausea, vomiting, headache, dizziness, mental confusion, gastrointestinal haemorrhage.

Treatment for overdosage:

Emesis or gastric lavage if appropriate. Symptomatic and supportive measures.

Dosage and Administration

Adults : Oral, 25 mg two to four times daily, the dosage may be increased to 150 - 200 mg daily, if necessary, as tolerated.

Note: Some types of arthritis may require up to 2 weeks therapy for noticeable improvement and up to 1 month for maximum effectiveness.

The information given here is limited. For further information consult your doctor or pharmacist.

Storage : Store below 25°C. Protect from moisture.
Presentation/Packing : Capsule x 500's, 1000's, Blisters of 10 x 10's.

Product Registration holder: HOVID Bhd., 121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.
Manufactured by: HOVID Bhd., Lot 56442, 7 1/2 Miles, Jalan Ipoh/Chemor, 31200 Chemor, Malaysia.

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