

Indomethacin -B Capsule

Indomethacin 25 mg, Vitamin B1 (Thiamine hydrochloride) 50mg



Composition :

Each Indomethacin-B capsule contains indomethacin 25 mg, vitamin B1 (thiamine hydrochloride) 50 mg

Pharmacological effect:

Indomethacin is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits antipyretic and analgesic properties.

Indomethacin is a potent inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues. Vitamin B1 is a nerves pain reliever.

Indications :

1. Moderate to severe rheumatoid arthritis including acute flares of chronic disease.
2. Moderate to severe ankylosing spondylitis.
3. Moderate to severe osteoarthritis.
4. Acute painful shoulder (bursitis and/or tendinitis).
5. Acute gouty arthritis

Contraindications:

- indomethacin -B is contraindicated in patients with known hypersensitivity to active material or the excipients .
- Indomethacin-B should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.
- Indomethacin-B is contraindicated in the setting of coronary artery bypass graft (CABG) surgery

Warnings :

Indomethacin-B is used with caution in people with heart failure and hypertension.
Indomethacin -B can cause gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration.
Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury.
Skin reactions and blood disturbance rarely occur with indomethacin. Borderline elevations of one or more liver tests may occur with taking indomethacin.
Indomethacin -B should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with preexisting asthma.

Drug Interactions:

ACE-Inhibitors and Angiotensin II Antagonists :
NSAIDs may diminish the antihypertensive effect of these drugs.
Aspirin:

The use of indomethacin in conjunction with aspirin or other salicylates is not recommended. The incidence of gastrointestinal side effects was significantly increased with combined therapy.
Beta-Adrenoceptor Blocking Agents:

Blunting of the antihypertensive effect of beta-adrenoceptor blocking agents by indomethacin has been reported.

Digoxin :

Indomethacin increases the serum concentration and prolong the half-life of digoxin.

NSAIDs :

The concomitant use of indomethacin with other NSAIDs is not recommended

Oral Anticoagulants:

When any additional drug, including indomethacin, is added to the treatment of patients on anticoagulant therapy, the patients should be observed for alterations of the prothrombin time.

Probenecid:

When indomethacin is given to patients receiving probenecid, the plasma levels of indomethacin are likely to be increased.

Pregnancy and lactation :

- Pregnancy Category C

In late pregnancy, as with other NSAIDs, indomethacin should be avoided because it may cause premature closure of the ductus arteriosus.

Indomethacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

- Use in Nursing Mothers

Indomethacin is excreted in the milk of lactating mothers. Indomethacin is not recommended for use in nursing mothers.

Pediatric Use

Safety and effectiveness in pediatric patients 14 years of age and younger has not been established.

The suggested starting dose is 1 to 2 mg/kg/day Indomethacin given in divided doses. Maximum daily dosage should not exceed 3 mg/kg/day or 150 to 200 mg/day.

Side effects:

Nausea, vomiting , Dyspepsia (including indigestion , heartburn and epigastric pain), diarrhea, abdominal distress or pain, constipation, headache, dizziness , vertigo, somnolence, depression and fatigue including malaise and listlessness, tinnitus.

Dosage and administrations:

13- capsules daily with food or as directed by the doctor.

Packaging

Indomethacin-B carton package contains 30 capsules within 3 blisters.

Storage condition

Keep the product in a dry place at temperature (15 – 30)°C out of the reach of children.

- A medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers& Union of Arab Pharmacists

Reva Pharmaceutical Industry - Syria

