

**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>INDOREN CAPSULES</b> <b>(Indomethacin BP 25 mg)</b>
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**Pack Insert:**

**INDOREN**  
**COMPOSITION**  
Each capsule contains  
Indomethacin BP 25mg

**PHARMACOLOGY**  
Indomethacin is a non-steroidal anti-inflammatory drug (NSAID) that exhibits antipyretic and analgesic properties. Its mode of action, like that of other anti-inflammatory drugs, is not known. However, its therapeutic action is not due to pituitary-adrenal stimulation. Indomethacin is a potent inhibitor of prostaglandin synthesis in vitro. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Moreover prostaglandins are known to be among the mediators of inflammation. Since indomethacin is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

**INDICATIONS**  
Indomethacin has been found effective in active stages of the following:

- Moderate to severe rheumatoid arthritis including acute flares of chronic disease.
- Moderate to severe ankylosing spondylitis.
- Moderate to severe osteoarthritis.
- Acute painful shoulder (bursitis and /or tendonitis).
- Acute gouty arthritis.

**DOSAGE AND ADMINISTRATION**  
**Paediatric**  
Indomethacin ordinarily should not be prescribed for paediatric patients 14 years of age and under.

**Adult Use**  
25 to 75 mg 2-4 times daily.


**SIDE EFFECTS**  
Frequent side effects includes gastrointestinal disturbances, headache, dizziness, also gastrointestinal ulceration and bleeding, rarely drowsiness, confusion, insomnia, convulsions, psychiatric disturbances, depression, syncope, blood disorders (particularly thrombocytopenia), hypertension, hyperglycemia, blurred vision, corneal deposits, peripheral neuropathy, and intestinal strictures.

**PRECAUTIONS**  
A patient with symptoms and/or signs suggesting liver dysfunction  
Elderly patients seem to tolerate ulceration or bleeding less well than other individuals and many spontaneous reports of fatal GI events are in this population.

**CONTRAINDICATIONS**  
Indomethacin is contraindicated in patients with known hypersensitivity to indomethacin. Indomethacin should not be given to the patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Indomethacin is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

**Storage Conditions:**  
Store in a cool, dry place below 30°C. Protect from light.  
Keep out of reach of children.

**PRESENTATION**  
Jar of 1000 capsules  
Blister pack of 10x10 capsules.

**MANUFACTURED BY:**  
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*A Milestone To Golden Health*