This page contains medical information related to INDOMETHACIN CAPSULES. The text is too long to summarize in a natural form without context, but it appears to discuss various medical conditions and treatments, including:

- Cardiovascular Thrombotic Events
- Indications and Usage
- Dosing Instructions
- Contraindications
- Dosage Forms and Strengths
- Warnings and Precautions
- General Dosing Instructions
- Acute Gouty Arthritis
- Acute Painful Shoulder
- Moderate to Severe Osteoarthritis
- Moderate to Severe Rheumatoid Arthritis
- Premature Closure of Fetal Ductus Arteriosus
- Hepatotoxicity
- Hematologic Toxicity
- Ocular Effects
- Heart Failure and Edema
- Neutropenia
- Anaphylactic Reactions
- Serious Skin Reactions
- Premature Closure of Fetal Ductus Arteriosus

The text also mentions the risk of serious, irreversible, including fatal, adverse reactions and the importance of careful instructions to patients. It emphasizes the need for close monitoring and the necessity to report suspected adverse reactions. The text suggests that serious skin reactions are generally considered and the risk of serious skin reactions increases with duration of use. It also notes that INDOMETHACIN CAPSULES are not recommended for use in the setting of coronary artery bypass graft (CABG) surgery. The text is intended for healthcare professionals and patients.
The adverse reactions for indomethacin capsules listed in the following table have been arranged into
significantly higher in the group receiving indomethacin capsules than in the group taking indomethacin
indicated for long-term treatment.

5.1 Ocular Effects

- Headache. Headache which persists despite dosage reduction requires cessation of therapy with
  indomethacin capsules.
- Indomethacin capsules may cause drowsiness; therefore, caution patients about engaging in activities
  requiring alertness.
- Indomethacin capsules may aggravate depression or other psychiatric disturbances, epilepsy, and
  seizures.
- Blurred vision may be a significant symptom and warrants a thorough examination of the eye.
- Visual disturbances (including redness or watering of the eye, photophobia, increased tearing, and
  lacrimation) may diminish the utility of diagnostic signs in detecting infections.
- Hemolytic anemia, aplastic anemia, pernicious anemia, and megaloblastic anemia have been reported
  with indomethacin.
- Hemolytic anemia and aplastic anemia have been reported in patients with hemoglobinopathies
  receiving indomethacin.
- Concurrent use of indomethacin capsules with other medications that cause hematologic toxicity
  has increased the risk of hematologic side effects.
- Thrombocytopenia has been reported with indomethacin capsulrs.
- The risk of thrombocytopenia may be increased in patients with a history of thrombocytopenia or
  other episodes of unexplained thrombocytopenia.
- Hematologic toxicity may range from a mild decrease in the platelet count to severe, even fatal
  thrombocytopenia which may result in hemorrhagic complications.
- Hemolytic anemia may cause jaundice, rash, and other signs of bone marrow depression.
- Thrombocytopenia may cause bruising and bleeding, including gastrointestinal bleeding.
- The safety of indomethacin capsules in patients with hematologic abnormalities has not been
  established.
- Indomethacin capsules should be used with caution in patients with hematologic abnormalities.
- Monitor blood pressure (BP) during the initiation of NSAID treatment and throughout the course of
  therapy.
- NSAIDs, including indomethacin capsules, can lead to new onset of hypertension or worsening of
  preexisting hypertension, either of which may contribute to the increased incidence of CV events.
- NSAIDs, including indomethacin capsules, can lead to worsening of fluid retention and edema.

5.2 Gastrointestinal Bleeding, Ulceration, and Perforation

- Avoid the use of indomethacin capsules in patients with a recent MI unless the benefits are expected to
  outweigh the risk of worsening renal function. If indomethacin capsules are used in patients with
  renal impairment, monitor for the development of symptoms of HB.
- Patients with a prior history of peptic ulcer disease and/or GI bleeding who used NSAIDs had a greater
  risk of developing peptic ulcer disease and hemorrhage.
- NSAIDs, including indomethacin capsules, have been shown to increase the risk of MI, stroke, and
certain other cardiovascular events in patients with cardiovascular disease or certain risk factors for
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Females

This is 0.5% of the maternal weight-adjusted dosage or about 3% of the neonatal dose for treatment of

were measured in breast milk of eight postpartum women using doses of 75 mg daily and the results

In one study, levels of indomethacin in breast milk were below the sensitivity of the assay (<20 mcg/L)

Based on available published clinical data, indomethacin may be present in human milk. The

Based on animal data, prostaglandins have been shown

Reproductive studies were conducted in mice and rats at dosages of 0.5, 1.0, 2.0, and 4.0mg/kg/day.

Data

There are no studies on the effects of indomethacin capsules during labor or delivery. In animal studies,

0.05 times the MRHD, respectively [see

Table 1. Possible Significant Drug Interactions with Indomethacin

Table 2 Clinically Significant Drug Interactions with Indomethacin

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Gastrointestinal Bleeding, Ulceration, and Perforation

shortness of breath, weakness, or slurring of speech, and to report any of these symptoms to their health therapist.

before initiating therapy with indomethacin capsules and periodically during the course of ongoing prescription dispensed. Inform patients, families, or their caregivers of the following information.

17 PATIENT COUNSELING INFORMATION

Dispense in a tight, light-resistant container using a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light.

NDC 70771-1005-2 in cartons containing 100 (10 X 10) unit-dose blisters

NDC 70771-1005-5 in bottle of 500 capsules

Indomethacin Capsules USP, 25 mg are off-white to light yellow, free flowing granular powder filled slowly and the patients followed very closely for any possible adverse effects.

Indomethacin capsules may enable the reduction of steroid dosage in patients receiving steroids for the treatment of joints involved, and morning stiffness; by increased mobility as demonstrated by a decrease in the average number of exacerbations per month, and in the duration of exacerbations. The benefit of indomethacin capsules has been demonstrated in the treatment of patients with rheumatoid arthritis. One study showed a 47.8% decrease in joint swelling, in patients receiving 50 mg of indomethacin capsules daily.

Indomethacin capsules have been shown to be an effective anti-inflammatory agent, appropriate for long-term use in rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis.

14 CLINICAL STUDIES

Once the plasma clearance of indomethacin is linear, the AUC or the Cmax can be used to describe the exposure of the drug. The plasma drug concentration of the drug is proportional to the dosage level. The time course of plasma concentration of drug is similar to that of the drug concentration in the systemic circulation. The clearance of indomethacin is linear over the dose range of 7.5 to 200 mg/day.

Impairment of Fertility

Indomethacin did not have any mutagenic effect in bacterial (Ames test) or mammalian (CHO cells, V79 Chinese hamster cells) assays. Indomethacin had no effect on the sperm count in rats given oral doses of up to 300 mg/kg/day for 6 months. Indomethacin had no effect on the fertility of male rats given oral doses of up to 300 mg/kg/day for 6 months.

Carcinogenesis

The carcinogenic potential of indomethacin in rats and mice was studied in a two-year bioassay. Indomethacin did not cause any increase in the incidence of mammary tumors in rats. Indomethacin also did not cause any increase in the incidence of mammary tumors in mice. Indomethacin did not cause any increase in the incidence of any other tumor in either rats or mice.

13 NONCLINICAL TOXICOLOGY

See Table 2 for clinically significant drug interactions of NSAIDs with aspirin [see Drug Interactions (7)]

When NSAIDs were administered with aspirin, the protein binding of NSAIDs were reduced, although the clearance of free NSAID was not altered. The clinical significance of this interaction is not known.

Drug Interaction Studies

Pharmacokinetic differences due to race have not been identified.

The mean half-life of indomethacin is estimated to be about 4.5 hours.

Eighty percent of an oral dose is absorbed with peak plasma concentrations occurring at about 2 hours. The mean bioavailability of a 25 mg and 50 mg oral suspension is 77% and 90%, respectively.

The absorption of indomethacin is not significantly affected by the presence of food. Indomethacin is extensively metabolized in the liver and undergoes enterohepatic recycling. About 60% of an oral dose is recovered in urine as conjugates of each metabolite and of indomethacin are formed.

Indomethacin is primarily metabolized to desmethyl and desbenzoyl metabolites, all in the unconjugated form. Appreciable formation of glucuronide conjugates of these metabolites is also observed.

Indomethacin is an average 1.4 times those following the first dose.

Following oral administration of a single 12.5 mg dose of indomethacin to 12 healthy volunteers, the plasma concentration of indomethacin was 10% of the plasma concentration at the time of maximum drug concentration. The mean maximum plasma concentration of indomethacin was 1.5 mcg/mL. The plasma concentration of indomethacin was significantly reduced when indomethacin was coadministered with aspirin. The mean maximum plasma concentration of indomethacin was 1.0 mcg/mL.

Indomethacin capsules are bioequivalent to a 50 mg indomethacin capsules when each was administered with food. With a typical therapeutic regimen of 25 or 50 mg three times a day, the steady-state plasma concentrations of indomethacin were 1.5 and 2.0 mcg/mL, respectively. The mean maximum plasma concentration of indomethacin was 1.5 mcg/mL.

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What is the most important information I should know about Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs are medicines that block the effect of a naturally occurring chemical in the body called a "cyclooxygenase" or "COX" enzyme. These medicines are used to relieve pain, swelling, and fever that can occur with many different illnesses. NSAIDs are used to treat conditions like arthritis, gout, dental pain, and headaches.

The most common NSAIDs are aspirin, ibuprofen, naproxen, celecoxib, diclofenac, and indomethacin. Your healthcare provider may prescribe NSAIDs in many different forms, such as capsules, tablets, liquids, or creams. This Medication Guide is for indomethacin capsules, which contain the active ingredient indomethacin.

Patients who take NSAIDs must get certain information before starting treatment. This information is important to help you use your NSAIDs as safely as possible. Talk to your healthcare provider before you start taking indomethacin capsules. If you are unsure about any part of this Medication Guide, ask your healthcare provider or pharmacist to explain it to you.

Only take indomethacin capsules as directed. Do not take more of it or take it more often than your healthcare provider tells you to.

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<th>Ingredient Name</th>
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<td>ORAL</td>
<td>INDOMETHACIN</td>
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**Inactive Ingredients**

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<td>SILICON DIOXIDE</td>
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<tr>
<td>FD&amp;C YELLOW NO. 5</td>
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**Product Characteristics**

- **Color**: GREEN
- **Score**: no score
- **Shape**: CAPSULE
- **Size**: 19mm
- **Flavor**: Imprint Code: 294;50mg

**Packaging**

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**Marketing Information**

- **Marketing Category**: ANDA
- **Application Number or Monograph Citation**: ANDA090403
- **Marketing Start Date**: 07/21/2016

**Labeler**: Cadila Healthcare Limited

**Establishment**: Analysis, Manufacture