

Patient Information Leaflet
Indoren Capsules
Indomethacin BP 25 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

- a. What Indoren Capsules is and what it is used for
- b. Before you take Indoren Capsules
- c. How to take Indoren Capsules
- d. Possible side effects
- e. How to store Indoren Capsules
- f. Further information

a. What Indoren Capsules is and what it is used for

Indoren Capsules contain a medicine called Indomethacin. Indomethacin 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 orthopaedic procedures.
- treatment of pain and associated symptoms of primary dysmenorrhoea.

Since indomethacin is not a simple analgesic, its use should be limited to the above conditions.

b. Before you take Indoren Capsules

Do not take Indoren Capsules if you:

- are allergic (hypersensitive) to indomethacin or any other ingredients of this medicine (listed in section f). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- suffer from severe heart failure, a disease of the heart that causes shortness of breath and swelling of the feet or legs due to fluid buildup
- suffer from epilepsy (fits) or parkinsonism (disorder of the brain leading to tremor, stiffness and shuffling of the body)
- suffer from psychiatric disturbances (e.g. anxiety, depression, personality disorders)
- suffer from porphyria (disorder in which an important part of blood, heme, is not made properly)
- have taken another NSAID (including aspirin) or COX-2 inhibitor (NSAID that selectively blocks the COX-2 enzyme) and suffered an unpleasant or allergic reaction including skin rashes, swelling (especially of the throat) or a runny nose
- have a stomach ulcer or bleeding in your stomach, or have had two or more episodes of stomach ulcers, stomach bleeding or perforation
- suffer from any liver disease

- suffer from nasal polyps (growths within the nose)

Indoren Capsules is NOT recommended for use in children

If any of the above applies to you, you should NOT take Indoren Capsules. Tell your doctor immediately.

Take special care with Indoren Capsules if you:

- have any allergies
- suffer from asthma
- have kidney problems
- have bleeding disorders or blood clotting problems
- are taking other NSAIDs, including COX-2 selective inhibitors (NSAID that selectively blocks the COX-2 enzyme) and aspirin (a substance present in many medicines used to relieve pain and lower fever)
- suffer from any diseases of the bowel such as Crohn's disease or ulcerative colitis, gastrointestinal cancers, diverticulitis (inflamed or infected pouches/ pockets in the colon)
- suffer from any conditions of the liver or heart that causes fluid retention, or high blood pressure
- suffer with systemic lupus erythematosus (SLE) or any other connective tissue disorder
- currently have an infection (treated or not) or are receiving treatment with live vaccines
- are due to have an operation Tell your doctor if any of the above applies to you

Special Warning: Medicines such as Indoren Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription, herbal and homeopathic remedies.

It is especially important to mention if you are taking:

- aspirin or related medicines (salicylates) (used to relieve minor aches and pains, reduce inflammation and reduce fever)
- other NSAIDs including diflunisal
- antidepressants (e.g. selective serotonin reuptake inhibitors (SSRIs) e.g. citalopram, fluoxetine)
- corticosteroids (e.g. cortisone, prednisone)
- medicines to stop the blood clotting (e.g. Warfarin)
- medicines to treat diabetes (e.g. tolbutamide, chlorpropamide, glipizide)
- medicines to treat high blood pressure (e.g. furosemide, thiazide, triamterene, atenolol, bisoprolol, propranolol, captopril, quinipril, hydralazine, losartan, nifedipine)
- lithium or haloperidol (medicines to treat mental illness)
- anti-viral medicines (e.g. zidovudine or ritonavir)
- medicines to treat heart conditions (e.g. digoxin)
- immunosuppressive drugs e.g. ciclosporin or tacrolimus (used after an organ transplant operation in order to reduce the risk of organ rejection)

- methotrexate (used to treat some cancers, severe psoriasis and severe rheumatoid arthritis)
- desmopressin (hormone preparation used for night-time bed wetting)
- mifepristone (used to induce abortion)
- baclofen (muscle relaxant)
- pentoxifylline (used to improve blood flow through the blood vessels)
- probenecid (used to treat gout)
- antacids (used to relieve heartburn, upset stomach or acid indigestion)
- tiludronic acid (used to treat bone diseases)
- antibiotics (e.g. ciprofloxacin)

Pregnancy and breast-feeding

Do not take Indoren Capsules if you are pregnant or breast-feeding. Tell your doctor if you are planning to become pregnant or if you are having problems becoming pregnant. Always speak to your doctor or pharmacist before taking any medicine.

Warning: Indoren Capsules belongs to a group of medicines which may affect fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Indomethacin will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving or using machines

This medicine may make you feel drowsy, dizzy, tired or affect your vision. If affected, do not drive or operate machinery.

Effects on laboratory tests

If you need to have any tests such as blood or urine tests, tell the doctor that you are taking Indoren Capsules. You may need to stop taking these tablets before you have the test.

c. How to take Indoren Capsules

You should swallow the tablets whole with a glass of water with, or immediately after food. Always take Indoren Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Dosage

The dosage should be carefully adjusted according to the needs of the individual patient, starting with a low dose.

To reduce the possibility of gastro-intestinal disturbances, indomethacin capsules should always be taken with food, milk or immediately after meals, or with an antacid and in chronic conditions start the therapy with a low dosage, increasing as required.

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

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

Chronic rheumatic disorders: 25 mg 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, according to severity for 10-14 days. Normally 150mg daily, rarely 200mg daily.

Lumbago: 50mg two or three times daily, according to severity. 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 orthopaedic 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.

Dysmenorrhoea: Up to 75mg daily, starting with onset of cramps or bleeding, and continuing for as long as symptoms usually last.

Elders: Elders 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: Indomethacin is contraindicated in children as its safety has not been established.

Your doctor may advise you to take your medicine in a different way. You should always follow your doctor's advice about when and how to take your medicine and always read the label.

If you take more Indoren Capsules than you should

If you take more Indomethacin than you should, contact your doctor or go to the nearest hospital accident and emergency department immediately. If an overdose has been taken there may be signs such as headache, feeling sick or being sick, stomach pain or bleeding, drowsiness, dizziness, ringing in the ears or fainting.

If you forget to take Indoren Capsules

If you forget to take Indoren Capsules, take it as soon as you remember, unless it is almost time for your next dose. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Indoren Capsules

Indoren Capsules should only be used for the shortest period of time to control your symptoms. If you feel that you do not require the tablets anymore please talk to your doctor before you stop your treatment.

d. Possible side effects

Like all medicines Indoren Capsules can cause side effects in some patients, particularly when you first start taking it.

Stop taking Indoren Capsules and talk to your doctor immediately or go to your nearest hospital emergency department if you:

- have any allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- experience severe abdominal pains (pain in your stomach) or other abnormal stomach symptoms including inflammation of the mouth or guts, or worsening of these conditions and ulceration of the intestines which can cause bleeding, obstruction or can perforate (burst), worsening of Crohn's disease or ulcerative colitis

- pass blood in your faeces (stools/ motions)
- pass black tarry stools
- vomit blood or dark particles that look like coffee grounds
- suffer inflammation of the liver- symptoms include fever, fatigue, nausea, stomach pain, loss of appetite, dark coloured urine, light coloured stools, or jaundice (yellowing of the skin and whites of the eyes)
- develop aseptic meningitis- symptoms include headache, fever, stiff neck, tiredness, feeling ill, eyes become sensitive to bright light
- develop indigestion or heartburn

Warning: Medicines such as Indoren Capsules may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

Other possible side effects

- **Effects on the blood:** changes in the numbers and types of blood cells (this will be seen in the results of blood tests), bruising, sore throat, nose bleeds, infections
- **Effects on the nervous system:** fatigue, drowsiness, dizziness, headaches, problems with speech, fainting, nervousness, coma, light-headedness, vertigo, tiredness, hallucinations (seeing things that are not there), difficulty sleeping, depression, confusion, anxiety, mental disturbances, involuntary movements, loss of co-ordination, numbness and tingling, fits or worsening of fits and Parkinson’s syndrome (symptoms include tremor, stiffness and shuffling of the body)
- **Effects on the eye:** inflammation of the optic nerve (nerve connecting the eye and the brain). Symptoms include pain in and around the eye, blurred or double vision, sudden (complete or partial) loss of vision. Deposits on the front surface of the eye (cornea) or effects on the back surface of the eye (retina). Symptoms include pain in and around the eye, poor vision and bright flashes of light or floating black spots.
- **Effects on the ear:** ringing or buzzing or other hearing disturbances (rarely deafness)
- **Effects on the heart:** high or low blood pressure (symptoms include dizziness, fainting, light-headedness, nausea, heart attack), chest pains, fast or irregular heartbeats and heart failure (symptoms include shortness of breath, tiredness, increased heart rate, swelling (especially of the ankles))
- **Effects on the stomach:** feeling or being sick, abdominal pain or discomfort, indigestion, loss of appetite, constipation or diarrhoea, flatulence
- **Effects on the skin:** sensitivity to light, worsening of psoriasis
- **Effects on the kidneys:** inflammation of the kidneys- symptoms include lower back pain, fever, nausea, headache, cloudy or light red urine, pain while urinating. Kidney disease (symptoms include urinating more often, bloody urine, swelling in the ankles, legs, arms or hands) or kidney failure (symptoms include blood or protein in the urine and an increase in blood urea, weakness, muscle cramps)
- **Effects on the metabolic system:** changes in the level of some substances in the blood (e.g. sugar, potassium), may occur. This will be seen in the results of blood tests.
- **Other effects:** bleeding from the vagina, breast changes (enlargement, tenderness, breast development in men), flushing, sweating, mouth ulcers, muscle weakness and worsening of cartilage damage (damage of the tissue surrounding the surface of joints)

If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

e. How to store Indoren Capsules

Do not store above 30°C. Protect from light.

Keep out of reach of children.

Do not use your medicine after the expiry date stated on the label. The expiry date defers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

f. Further information

What Indoren Capsules contains

Each hard gelatin capsules contains Indomethacin BP 25 mg.

The other ingredients are Maize starch, Microcrystalline cellulose, Purified talc and Sodium starch glycolate.

What Indoren Capsules looks like and contents of the pack

Indoren Capsules: Ivory/ Ivory coloured size '3' capsules with imprinted on body 25 and INDO on cap, containing white coloured powder.

Indoren Capsules: Aluminium/PVC blister strip of 10 capsules and 10 of such blister strips are packed in a unit box with pack insert.

MANUFACTURED BY

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A milestone to Golden Health