

PACKAGE LEAFLET: INFORMATION FOR THE USER

INDOMETACIN

25mg CAPSULES

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Indometacin is and what it is used for
2. Before you take Indometacin
3. How to take Indometacin
4. Possible side effects
5. How to store Indometacin

1. WHAT INDOMETACIN IS AND WHAT IS IT USED FOR

Indometacin belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Indometacin works by reducing inflammation and relieving pain, swelling and stiffness in the joints and muscles. Indometacin is used to relieve some symptoms caused by:

- acute gout (pain and inflammation of the joints)
- rheumatoid arthritis
- osteoarthritis
- acute musculoskeletal disorders (e.g. sprains, strains and other injuries, such as backache and neckache)
- ankylosing spondylitis (arthritis of the spine)

2. BEFORE YOU TAKE INDOMETACIN DO NOT

Take Indometacin if you:

- are allergic (hypersensitive) to indometacin or any other ingredients in these capsules.

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 build up
- 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)

Indometacin is NOT recommended for use in children.

If any of the above applies to you, you should NOT take Indometacin. Tell your doctor IMMEDIATELY.

Take special care with Indometacin 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 Indometacin 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 Indometacin 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: Indometacin belongs to a group of medicines which may affect fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Indometacin 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 Indometacin. You may need to stop taking these tablets before you have the test.

3. HOW TO TAKE INDOMETACIN

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

DOSAGE

Adults

- The usual dosage is one capsule taken two to three times daily. This can be increased by one capsule weekly until the total daily dose is 100mg to 200mg.

Elderly

- If you are elderly your doctor may prescribe a lower daily dose and reduce the duration of treatment. Your doctor will see you more often while you are taking this medicine.

Children

- Indometacin is not recommended for use in children.

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 Indometacin than you should

If you take more Indometacin 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 Indometacin

If you forget to take Indometacin, 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 Indometacin

Indometacin 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.

4. POSSIBLE SIDE EFFECTS

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

STOP taking Indometacin 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 Indometacin 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.

5. HOW TO STORE INDOMETACIN

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep the capsules in the original container.

Protect your medicine from light, heat (store below 25oC) and moisture.

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.

This leaflet was last revised August 2011