

Package leaflet: Information for the user**INDOMETACIN 25 MG CAPSULES**

Indometacin

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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Indometacin Capsules are and what they are used for
2. What you need to know before you take Indometacin Capsules
3. How to take Indometacin Capsules
4. Possible side effects
5. How to store Indometacin Capsules
6. Contents of the pack and other information

1. What Indometacin Capsules are and what they are used for

The name of your medicine is Indometacin 25 mg Capsules. The active ingredient is Indometacin. Indometacin Capsules belong to a group of medicines called non steroidal anti-inflammatory drugs (NSAIDs). These work by reducing the body's ability to produce inflammation, which may cause pain and discomfort.

Your doctor has prescribed Indometacin for you because you are suffering from one of the following:

- Rheumatoid arthritis
- Osteoarthritis
- Pain and stiffness in the backbone (ankylosing spondylitis)
- Musculoskeletal disorders
- Lower back pain
- Pain, inflammation and swelling following muscle or bone surgery
- Period pain
- Disease of the hip joint

In addition, Indometacin capsules may be prescribed for acute gouty arthritis.

2. What you need to know before you take Indometacin Capsules**Do not take Indometacin capsules if you:**

- are in the last three months of pregnancy or while breast-feeding (see 'Pregnancy and breast-feeding')
- are allergic (hypersensitive) to indometacin or any of the ingredients of Indometacin capsules (see Section 6)

- are allergic (hypersensitive) to aspirin, ibuprofen or other NSAIDs or you have developed signs of asthma (wheezing), runny nose, swelling of the face, lips, tongue or throat or a skin rash with pale or red irregular raised patches with severe itching, when taking these medicines
- are taking other NSAIDs (e.g. naproxen) including COX II inhibitors (e.g. celecoxib)
- suffer with angioneurotic oedema (swelling of the face, lips, tongue or throat)
- have or have had a history of two or more episodes of peptic ulcers (ulcer in your stomach or duodenum) or bleeding in your stomach or intestines in the past. Symptoms may include vomiting particles that look like coffee-grounds, black tarry stools and blood in your faeces (stools/motions)
- have nasal obstruction (nasal polyps)

Warnings and Precautions

If you are elderly or you have previously had stomach ulcers, you have a higher risk of getting side effects, especially from the stomach. Your doctor should therefore prescribe the lowest dose that gives you sufficient relief. If you experience any usual symptoms from the stomach, you must tell your doctor about it.

Medicines such as Indometacin may be linked to a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Taking pain killers for headaches too often or for too long can make them worse.

Tell your doctor before you take this medicine if you:

- have heart problems, previous stroke or think you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- are elderly, have ulcerative colitis or Crohn's disease, as there is a higher risk of stomach problems (e.g. ulcers or bleeding)
- have or have had any problems with your liver, heart or kidneys that may cause fluid retention
- have asthma, mental health problems, epilepsy or Parkinson's disease (tremor, stiffness and shuffling)
- have blood clotting problems or are taking medicines to stop your blood clotting
- have an infection or are being treated for an infection, or are receiving treatment with live vaccines
- have a connective tissue disorder including Systemic Lupus Erythematosus, which may cause joint pain, skin rashes and fever
- are a woman trying to become pregnant or undergoing investigation for infertility. Indometacin may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant
- are taking medicines poisonous to the kidneys such as cisplatin or vancomycin

- have an infection or sepsis (severe infection)
- have a decreased amount of fluid around the cells of the body (extracellular volume depletion)
- have peripheral arterial disease (a problem with the circulation in the legs).
- If you are in the third trimester of pregnancy or while you are breastfeeding (see pregnancy, breast feeding and fertility)

Tests and Surgery

Indometacin may alter the results of some blood, liver or kidney. If you go into hospital, or are about to have, or have recently had surgery, or have treatment for other conditions, tell the doctor that you are taking Indometacin.

Regular blood and eye tests are recommended when taking this medicine for prolonged treatment.

Use in children and adolescents

Indometacin capsules must not to be used in children.

Other medicines and Indometacin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they **may affect how Indometacin works:**

- other medicines for pain and swelling including NSAIDs, aspirin, Naproxen or COX II inhibitors (e.g. Celecoxib) or diflunisal (for pain and inflammation)
- medicines for high blood pressure or heart conditions, such as captopril and lisinopril (ACE inhibitors), doxazosin and prazosin (alpha-blockers), atenolol and propranolol (beta-blockers), candersatan and losartan, hydralazine, nifedipine, pentoxifylline or digoxin
- medicines to increase urine production (diuretics), such as furosemide and triamterene
- medicines used to thin the blood and stop blood clots from forming such as anti platelet medicines or coumarins, heparins, phenindione and warfarin
- medicines to treat cancer such as methotrexate or cyclophosphamide
- quinolone antibiotics (e.g. Ciprofloxacin) to treat bacterial infections
- selective Serotonin Reuptake Inhibitors (SSRIs) for depression
- phenytoin (for epilepsy)
- diazepam (for anxiety, difficulty sleeping, alcohol withdrawal, seizures and muscle spasm)
- steroids to treat swelling and allergies
- metformin or sulphonylureas e.g. gliclazide for diabetes
- ciclosporin or tacrolimus or Muromonab-CD3 to suppress the immune system and stop the rejection of organs after transplants
- haloperidol (an antipsychotic drug) or lithium for mental health problems
- zalcitabine, ritonavir or zidovudine to treat viral infections
- cardiac glycosides e.g. digoxin (for heart failure and irregular heartbeat)

- pentoxifylline (for blood vessel disease and leg ulcers)
- antacids (used to relieve heartburn, upset stomach or acid indigestion)
- baclofen, a muscle-relaxant
- desmopressin used to control night-time bed wetting
- mifepristone for abortion. Indometacin capsules should not be taken within 8-12 days of taking mifepristone
- probenecid to treat gout
- tiludronic acid to treat bone disease.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine. Pregnancy

Do not take indometacin if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take indometacin during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, indometacin can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Breast-feeding is not recommended if you are taking indometacin. Indometacin is known to pass into breast milk.

Female fertility

Indometacin may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Indometacin can cause headaches, dizziness, drowsiness and visual disturbances in some people. If this happens to you, avoid activities which require you to be alert; for example, driving a car and operating machinery.

Indometacin Capsules contain Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content:

Indometacin capsules contains less than 1 mmol sodium (23 mg) per capsules, that is to say essentially 'sodium-free'.

FLAT DIMENSION = 180 x 480mm

FOLDED DIMENSION = 180 x 30mm

3. How to take Indometacin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take with or after food.

The amount you take will depend upon your condition.

The recommended dose

Chronic condition: In chronic conditions, starting therapy with a low dosage, increasing this gradually as necessary, and continuing a trial of therapy for an adequate period (in some cases, up to one month) will give the best results with a minimum of unwanted reactions. The recommended oral dosage range is 50 mg to 200 mg daily in divided doses. Paediatric dosage not established.

Dosage in dysmenorrhoea: Up to 75 mg a day, starting with onset of cramps or bleeding, and continuing for as long as the symptoms usually last.

Dosage in acute gouty arthritis: 150 mg to 200 mg daily in divided doses until all symptoms and signs subside.

Adults: The recommended adult dosage is between 50 and 200 mg a day.

Children: Not recommended for use in children.

Elderly: Indometacin should be used with particular care in older patients who are more prone to adverse reactions.

If you take more Indometacin Capsules than you should

If you take too many capsules by mistake or someone else accidentally takes your capsules, contact your doctor immediately or go to the nearest casualty department.

Symptoms of overdose include; feeling or being sick, headache, abdominal pain, diarrhoea, dizziness, drowsiness, fainting, disorientation, excitement, coma, ringing or buzzing in the ear, kidney failure, liver damage.

If you forget to take Indometacin Capsules

If you forget to take, take it as soon as you remember. If it is nearly time for your next dose, just carry on with the next dose as normal.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

If you stop taking Indometacin capsules

You should take Indometacin capsules for as long as your doctor tells you to. It may be dangerous to stop taking them without your doctor's advice.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following serious side effects, STOP TAKING this medicine and seek immediate medical help:

- pass blood in your stools, pass black tarry stools, vomit blood or dark particles that look like coffee grounds. These symptoms may indicate bleeding in the stomach or intestines.
 - an allergic reaction
- Allergic reactions may cause:
- wheezing, asthma, difficulty breathing or shortness of breath, swelling and irritation inside the nose
 - swelling of eyelids, lips, tongue, throat, hands, feet or ankles
 - indigestion, heartburn, aches and pains in the stomach area.

These symptoms may indicate an ulcer in the stomach or intestines

- aseptic meningitis which may cause stiff neck, headache, vomiting, nausea, feeling or being sick, fever disorientation, especially in those who already have an auto-immune disease such as systemic lupus erythematosus or mixed connective tissue disease
- inflammation, damage or failure of the kidneys
- sugar, protein or blood in your urine
- altered liver function
- inflammation of the liver (hepatitis) which may cause loss of appetite, abdominal discomfort, dark urine and yellowing of the skin and whites of the eyes (jaundice)
- change in level of other types of blood cells that may cause bleeding, bruising, fever, frequent infections or sore throats.

Tell your doctor as they may wish to test your blood

- nosebleeds, blood clotting throughout the body, disturbance of blood count, reduction in blood cell production by the bone marrow
- ringing in the ears, hearing disturbances including rarely deafness
- inflammation of the optic nerve that may cause sudden loss in vision or pain on movement of the eye
- inflammation of the pancreas, which can cause severe pain in the abdomen and back
- bleeding from the vagina
- blister on the skin that are red, flaky or peeling, such as severe rash involving reddening, peeling, swelling of the skin, that resembles sever skin burns (toxic epidermal necrolysis), circular irregular red patches on the skin of the hands and arms (erythema multiforme) sever skin rash with flushing fever blisters or ulcers (Stevens Johnson syndrome).

Other side effects:

Effects on the heart and circulatory system:

- flushing, fluid retention, low or high blood pressure (hypotension or hypertension)
- chest pain, or a fast or irregular heartbeat, palpitations
- heart failure, or a small increased risk of heart attack or stroke

Effects on blood:

- reduction in red blood cells (anaemia), which can make the skin pale and cause weakness or breathlessness
- high levels of potassium (hyperkalaemia) or sugar (hyperglycaemia) in the blood

Effects on the Brain and central nervous system:

- depression, anxiety, disorientation, hallucinations, confusion, nervousness, lack of self-awareness
- a feeling of dizziness or spinning (vertigo)
- speech problems
- numbness or tingling, involuntary movements, fits, worsening of epilepsy or Parkinson's disease
- feeling unwell, tiredness, weakness, difficulty sleeping, headache, dizziness, drowsiness, light-headedness, loss of onscious, build up of fluid in the brain, coma

Effects on the eye:

- blurred vision, double-vision
- pain in and around the eye
- deposits on the front surface of the eye (cornea), disorders of the back surface of the eye (retina)

Effects on the stomach and intestines:

- painful inflamed mouth ulcers
- loss of appetite, feeling or being sick, diarrhoea, gas constipation
- developing or worsening of ulcerative colitis or Crohn's disease
- inflammation of the lining of the stomach or a portion of the small intestine, an obstruction in the intestines

Effects on the skin:

- worsening of psoriasis
- hair loss, sweating
- itching, rash
- tender red lumps under the skin
- sensitivity to sunlight or artificial light (e.g. sun beds)

Effects on the muscles and bones:

- muscle weakness, accelerated deterioration of cartilage

Effects on the breasts and reproductive system:

- enlargement or tenderness of the breasts, breast development in men.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Indometacin Capsules

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Protect from light.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Indometacin Capsules contain

- The active substance is 25 mg of Indometacin
- The other ingredients are: lactose, maize starch, sodium glycolate, magnesium stearate, gelatin and titanium dioxide (E171).

What Indometacin Capsules look like and contents of the pack

- The capsules are white and printed with BL 25 containing a white powder.
- They are available in packs of 28, 250 or 500 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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