

- **Blood:**
 - small purple red spots, nosebleeds, bruising, disorder characterised by blood spots, blood clotting throughout the body, disturbance of blood count, reduction in blood cell production by the bone marrow. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.
- **Metabolism:**
 - high blood sugar
 - sugar in the urine
 - high blood levels of potassium (muscle cramps or pain, irregular heart beat, unusual tiredness or weakness).
- **Nervous system:**
 - headache, dizziness, lightheadedness, spinning sensation (vertigo), tiredness, fainting, a feeling of general discomfort and illness, drowsiness, coma, fluid in the brain causing swelling
 - depression, nervousness, confusion, hallucinations, anxiety and other mental health problems, a feeling of unreality (that the mind is separated from the body), difficulty sleeping
 - speech disorder, fits or seizures, worsening of epilepsy, disorder of the nerves causing tingling and numbness, pins and needles
 - uncontrolled movements, worsening of parkinsonism (tremor, stiffness and shuffling).
- **Heart:**
 - fluid retention causing swelling, chest pain, heart failure
 - high and low blood pressure
 - racing heart beat, irregular heart beat, palpitations
- **Blood vessels:**
 - flushing.
- **Breathing:**
 - increase in the number of white blood cells in the lungs
 - narrowing of the airways in those who have a history of asthma or allergic disease.
- **Stomach and intestines:**
 - loss of appetite
 - development or worsening of ulcerative colitis or Crohns disease
 - inflammation of the pancreas causing pain and tenderness in the abdomen and back (pancreatitis).
- **Skin:**
 - inflammation of blood vessels
 - sensitivity to sunlight or artificial light (e.g. sun beds)
 - tender red lumps usually on the legs (erythema nodosum)
 - hair loss, sweating
 - worsening of psoriasis (itchy scaly pink patches on the elbows, knees, scalp and other parts of the body).

- **Liver:**
 - blocked bile flow (pale coloured stools, dark urine, itching).
- **Muscle and bone:**
 - muscle weakness, increased breakdown of cartilage.
- **Kidneys:**
 - blood in the urine
 - nephrotic syndrome (increased protein in urine and fluid retention)
 - too much protein in the urine
 - inflammation of the kidneys, reduced kidney function or kidney failure.
- **Reproductive system:**
 - bleeding from the vagina
 - breast enlargement or tenderness, enlarged breasts in men.

If you notice any of these side effects, or they get worse or you notice any side effects not listed, please tell your doctor or pharmacist.

5 How to store Indometacin capsules

Keep out of the reach and sight of children. Store below 25°C in a dry place. Protect from light. Do not take Indometacin capsules after the expiry date which is stated on the label/carton/bottle. 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 to protect the environment.

6 Further information

What Indometacin capsules contain

- The active substance (the ingredient that makes the medicine work) is indometacin PhEur. Each capsule contains either 25mg or 50mg indometacin.
- The other ingredients are starch 1500, powdered cellulose, colloidal silicon dioxide, magnesium stearate, yellow iron oxide (E172), titanium dioxide (E171), gelatin, shellac glaze, iron oxide black (E172), propylene glycol.

What Indometacin capsules look like and contents of the pack

Indometacin capsules are ivory, hard, gelatin capsules. Pack size is 28.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.

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If you would like a leaflet with larger text, please contact 01271 311257.

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Actavis, Barnstaple, EX32 8NS, UK

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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 any further questions, ask your doctor or pharmacist.
- 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.
- 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.

In this leaflet:

- 1 What Indometacin capsules are and what they are used for
- 2 Before you take Indometacin capsules
- 3 How to take Indometacin capsules
- 4 Possible side effects
- 5 How to store Indometacin capsules
- 6 Further information

1 What Indometacin capsules are and what they are used for

Indometacin capsules belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are pain killers which reduce swelling.

Indometacin capsules are for:

- inflammatory diseases of the joints such as rheumatoid arthritis, osteoarthritis and degenerative hip disease
- pain and stiffness in the backbone (ankylosing spondylitis)
- sprains and strains (acute muscle and bone disorders)
- lower back pain
- pain and swelling following muscle or bone surgery
- period pain
- gout.

Indometacin 25mg and 50mg capsules

2 Before you take Indometacin capsules Do not take Indometacin capsules if you:

- are in the **last three months of pregnancy**
- 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 ulcer** (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 severe **liver, kidney or heart** problems
- have **nasal obstruction** (nasal polyps).

Indometacin capsules must not be used in children.

Check with your doctor before taking Indometacin capsules if you are:

- **elderly** (see "Other warnings")
- to have a **vaccination** with a live vaccine
- 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
- taking medicines **poisonous to the kidneys** such as cisplatin or vancomycin.

or if you have:

- a history of **high blood pressure** or congestive **heart failure**
- a **bleeding or blood clotting** disorder
- a **mental health** problem e.g. mood changes
- **epilepsy**
- **Parkinson's Disease** (tremor, stiffness and shuffling)
- an **infection or sepsis** (severe infection)

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- any **liver, kidney or heart** problems
- **fluid retention** which may be caused by diseases of the heart or kidneys
- **asthma** or a history of **asthma**
- have or have a history of gastrointestinal diseases such as **ulcerative colitis** or **Crohn's disease**
- **systemic lupus erythematosus (SLE)** or other **connective tissue disorders**
- **diabetes**
- a **decreased amount of fluid** around the cells of the body (extracellular volume depletion)
- **peripheral arterial disease** (a problem with the circulation in the legs).

Other warnings

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 unusual symptoms from the stomach, you must tell your doctor about it.

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 you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

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

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, particularly:

- other non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin, naproxen or COX II inhibitors (e.g. celecoxib) or diflunisal (for pain and inflammation)
- quinolone antibiotics e.g. ciprofloxacin (to treat infections)
- medicines which thin the blood or which prevent blood clotting, such as warfarin or antiplatelet drugs such as clopidogrel
- selective serotonin reuptake inhibitors (SSRIs) e.g. fluoxetine (for depression)
- metformin or sulphonylureas e.g. gliclazide (for diabetes)
- phenytoin (for epilepsy)
- diazepam (for anxiety, difficulty sleeping, alcohol withdrawal, seizures and muscle spasm)
- medicines used to treat high blood pressure such as beta blockers (e.g. atenolol), alpha blockers (e.g. prazosin), ACE inhibitors (e.g. lisinopril), angiotensin II receptor antagonists (e.g. valsartan), hydralazine (vasodilator) or nifedipine

- haloperidol (an antipsychotic drug)
- zalcitabine, zidovudine or ritonavir (for HIV infection)
- cardiac glycosides e.g. digoxin (for heart failure and irregular heart beat)
- ciclosporin, tacrolimus or muromonab-CD3 (to suppress the immune system)
- corticosteroids e.g. prednisolone (used in many different diseases)
- cyclophosphamide or methotrexate (to treat some types of cancer and rheumatoid arthritis)
- desmopressin (for diabetes insipidus and frequent urination during the night)
- diuretics (water tablets) such as triamterene, thiazides (e.g. bendroflumethiazide) or furosemide
- lithium (for some mental health problems)
- mifepristone (for termination of pregnancy). Indometacin capsules should not be taken within 8-12 days of taking mifepristone
- baclofen (a muscle relaxant)
- pentoxifylline (for blood vessel disease and leg ulcers)
- probenecid (for gout)
- tiludronic acid (for Paget's disease of bone).

Pregnancy and breast-feeding

If you are in the last three months of pregnancy, you **must not** take Indometacin capsules. You **should only** take Indometacin capsules in the first six months of pregnancy or if you are breast-feeding under medical supervision. Always ask your doctor before taking any medicine.

Driving and using machines

Indometacin capsules may make you feel, drowsy, dizzy or affect your vision. Make sure you are not affected before you drive or operate machinery.

Tests

Your doctor may want to carry out tests to monitor your kidney and liver function, the levels of blood cells and the effects on your stomach and intestines (especially if you are elderly). If you have or have had a history of high blood pressure or heart failure your doctor may also want to monitor you. If you have rheumatoid arthritis you may be advised to have regular eye tests to check your sight.

Surgery

If you are about to have, or have recently had **surgery**, please contact your doctor before using this medicine.

3 How to take Indometacin capsules

Always take Indometacin capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the capsules with or after **food, milk or antacids** (indigestion remedy) to reduce side effects on the stomach and intestines.

Dose

• Adults:

- **Acute rheumatoid arthritis:** initially 25mg two or three times a day.
- **Chronic joint disorders:** 25mg two or three times a day. Your doctor may increase your dose depending on your response, up to a maximum of 200mg a day.
- **Sudden worsening of a chronic disorder:** up to 150-200mg a day. Your doctor will decide on the best dose for you.
- **Acute muscle and bone disorders:** initially 50mg two or three times a day for 10-14 days. Your doctor will decide on the best dose for you, depending on the severity of your condition.
- **Lower back pain:** 50mg two or three times a day for 5-10 days. Your doctor will decide on the best dose for you, depending on the severity of your condition.
- **Acute attack of gout:** 50mg three or four times a day until symptoms decrease.
- **After muscle or bone surgery:** 100-150mg a day in divided doses, to be taken until symptoms decrease.

• Elderly:

If you are elderly, your doctor will give you the lowest effective dose for the shortest amount of time.

• Children:

Indometacin capsules must not be used in children.

If you take more Indometacin capsules than you should

It is important not to take too many capsules. Contact your doctor or nearest hospital casualty department **immediately**, if you have taken more capsules than you should or a child accidentally swallows any.

Symptoms of overdose are headache, feeling or being sick, stomach pain, bleeding in the stomach or intestines, diarrhoea, disorientation, excitement, coma, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits or seizures, kidney failure, liver damage.

If you forget to take Indometacin capsules

If you forget to take your capsules, take the missed dose as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for one you have missed.

4 Possible side effects

Like all medicines, Indometacin capsules can cause side effects, although not everybody gets them.

STOP TAKING the medicine and seek immediate medical help if you develop any of the following at any time during your treatment:

• signs of bleeding in the stomach:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

• signs of an allergic reaction:

- difficulty breathing or swallowing, asthma, sudden decrease in blood pressure
- swelling of the face, lips, tongue or throat.

STOP TAKING the medicine and tell your doctor if you experience:

- **indigestion or heartburn**
- **abdominal pain** (pains in your stomach) or other abnormal stomach symptoms
- **effects on the stomach** such as feeling or being sick, inflammation of the stomach lining, small intestine or mouth, constipation, diarrhoea, wind, perforation of previous intestinal damage, narrowing of or blockage in the intestine
- **abnormal liver function** (as seen in blood tests)
- **liver disease:** yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis) causing fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever
- **skin reactions** such as itching, pale or red irregular raised patches with severe itching (hives), disorder characterised by blood spots, bruising and discolouring of the skin (purpura), blisters or skin that is red, flaky or peeling such as severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), circular, irregular red patches on the skin of the hands and arms (erythema multiforme), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome)
- **aseptic meningitis** (stiff neck, headache, 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.

Medicines such as Indometacin may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (see Section 2 'Other warnings').

Tell your doctor or pharmacist if you notice any of the following side effects:

• Eyes:

- blurred and double vision
- inflammation of the optic nerve (which may cause eye pain and loss of vision)
- eye pain
- changes in your sight.

• Ear:

- ringing or buzzing in the ears
- hearing disturbances including deafness.