

PACKAGE LEAFLET: INFORMATION FOR THE USER
Indocid Capsules 25mg and 50mg
Indocid-R 75mg Capsules (sustained release)
Indomethacin

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
- 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:

1. What Indocid Capsules are and what they are used for
2. Before you take Indocid Capsules
3. How to take Indocid Capsules
4. Possible Side Effects
5. How to store Indocid Capsules
6. Further Information

1. WHAT INDOCID CAPSULES ARE AND WHAT THEY ARE USED FOR

The active ingredient in your medicine is indomethacin. This belongs to a group of medicines known as ‘non-steroidal anti-inflammatory agents’ or NSAIDs. These work by reducing the body’s ability to produce inflammation, which may cause pain and discomfort.

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

- Rheumatoid arthritis.
- Osteoarthritis.
- Ankylosing spondylitis.
- Pain, inflammation, and swelling following orthopaedic surgery.
- Musculoskeletal disorders.
- Period pain.
- Low back pain.
- Disease of the hip joint.

In addition, Indocid Capsules (but not Indocid-R Capsules) may be prescribed for acute gouty arthritis.

2. BEFORE YOU TAKE INDOCID CAPSULES

Do not take Indocid capsules

- If you are hypersensitive (allergic) to indomethacin or any of the other ingredients in Indocid Capsules (for example, if you have experienced breathing difficulties, skin rashes which look like nettle rash, or a runny nose) or if you are hypersensitive to aspirin or another non-steroidal anti-inflammatory medicine.
- If you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two episodes of peptic ulcers, stomach bleeding or perforation.
- If you have polyps in your nose, associated with itching, nettle rash, wheezing, or swelling of the face, lips, tongue and/or throat or difficulties in swallowing or breathing

Take special care with Indocid capsules

Tell your doctor before taking these capsules if you:

- are epileptic
- have Parkinson's disease
- have a psychiatric problem
- have heart disease, high blood pressure or have a tendency for fluid retention
- are being treated for infection or you have a fever
- know you suffer from asthma, digestive tract, liver or kidney disease, diabetes or heart failure
- have a problem with your blood clotting.

If you have rheumatoid arthritis your doctor may want to examine your eyes at intervals during your treatment with Indocid. You should see your doctor if you notice any change in your vision.

Medicines such as Indocid may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If 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.

If you are having blood tests, make sure that the doctor doing them knows that you are taking Indocid.

Taking other medicines

Please tell your doctor if you are taking any of the following medicines:

- Aspirin or similar medicines.
- Other non-steroidal anti-inflammatory medicines including diflunisal.
- Anticoagulants, which thin the blood.
- A medicine for gout called probenecid.
- Methotrexate, a drug used in the treatment of cancer, severe skin disease and rheumatoid arthritis.
- Cyclosporin, a drug used to prevent the body from rejecting a recent organ or bone-marrow transplant, and to treat severe skin disease and rheumatoid arthritis.
- Lithium for treatment of mental disorders.
- Diuretics (water tablets).
- Cardiac glycosides, such as digoxin, medicines used in the treatment of congestive heart failure and certain alterations of heart rhythm.
- Antihypertensive medicines for the treatment of high blood pressure.
- A nasal decongestant called phenylpropanolamine usually found in over-the-counter cold relief preparations.
- Corticosteroid drugs, including anti-inflammatory and replacement therapies.
- Mifepristone, a treatment used in emergency for termination of pregnancy.
- Antibiotics from the quinolone group of antibiotics.

Pregnancy and Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, are planning to become pregnant or if you are breast-feeding. Indocid 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

Indocid 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.

3. HOW TO TAKE INDOCID CAPSULES

Always take Indocid capsules exactly as your doctor has told you. You should 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 usual adult dosage is between 50 and 200 mg a day.

With Indocid-R Capsules, this means the usual adult dosage is one or two capsules a day.

Not recommended for use in children.

If you take more Indocid 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.

If you forget to take Indocid 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 use an extra capsule to make up for forgotten doses.

If you stop taking Indocid capsules

You should take Indocid 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, Indocid can cause side effects although not everybody gets them.

If you experience an allergic reaction, STOP TAKING the medicine and seek immediate medical help:

Serious allergic reactions include itching; rashes; sensitivity to sunlight; loss of hair; swollen face, lips, tongue and throat; difficulty in breathing and swallowing; inflammation of blood or lymph glands; severe light headedness or dizziness due to a rapid fall in blood pressure. The allergic reaction may include problems with the liver, kidneys or blood cells (see above for symptoms of each).

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

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

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.

Medicines such as Indocid may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Common (affecting less than 1 in 10 patients receiving the medicine)

- Headache, dizziness, light-headedness, depression, vertigo and tiredness (including feeling unwell and listlessness).
- Nausea, loss of appetite, vomiting, trapped wind, constipation, and diarrhoea. Ulcers may develop with symptoms of stomach pain and bleeding.

Uncommon (affecting less than 1 in 100 patients receiving the medicine)

- Anxiety, confusion, fainting, drowsiness, convulsions, coma, loss of sensation, muscle weakness, involuntary muscle movements, sleeplessness, hallucinations and mental disorders.
- Pins and needles, speech problems, worsening of epilepsy (fits), tremor, stiffness and shuffling which can be temporary and often disappear with continued or reduced dosage.
- Inflammation of the mouth and stomach, wind, narrowing and/or obstruction of the intestines which may be seen as a swollen abdomen, and vomiting.
- High or low blood pressure, abnormal heartbeat, chest pain, palpitations, heart failure, kidney problems which can lead to water retention, reduction in the amount of urine passed, protein and blood in the urine, increased levels of urea in the blood. These changes in urine and blood composition would normally be picked up in urine or blood tests.
- Blood disorders which are usually detected in blood tests, but may be seen as pallor, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after injury. Difficulty in breathing may occur in patients already suffering from asthma or allergies.
- Blurred vision, double vision, pain in the eye and other visual disturbances.
- Ringing in the ears and other hearing disturbances.

Rare (affecting less than 1 in 1000 patients receiving the medicine)

- Intestine ulcers.
- Inflammation of the liver and jaundice, symptoms of which may be yellowing of the eyes and skin caused by liver and blood problems.
- Deafness.
- Increase protein in urine measured by a urine test, inflammation of the kidney which can cause swollen ankles or high blood pressure.
- Bleeding from the vagina in women; flushing and sweating; bleeding from the nose; breast changes including enlargement and tenderness in men and women; and ulcers in the lining of the mouth.
- Increased levels of sugar in the blood, sugar in the urine, high levels of potassium in the blood, which are generally diagnosed by laboratory tests.

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.

5. HOW TO STORE INDOCID CAPSULES

Keep out of the reach and sight of children.

Do not use Indocid capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store above 25°C.

Store in the original package to protect from light

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 Indocid capsules contain**

The active ingredient in Indocid Capsules and Indocid-R Capsules is indomethacin

Indocid Capsules come in two strengths. The ivory opaque capsules marked 'MSD 25' contain 25 mg indomethacin. The ivory opaque capsules marked 'MSD 50' contain 50 mg indomethacin.

Indocid-R is an ivory and transparent capsule carrying white and blue pellets marked 'MSD 693' and contains 75 mg indomethacin.

Indocid 25mg and 50mg Capsules contain: colloidal silicon dioxide, lactose, liquid lecithin concentrate, magnesium stearate E572, gelatin, titanium dioxide E171 and yellow ferric oxide E172.

Indocid-R capsules also contain: indigo carmine E132, magnesium stearate E572, maize starch, methylhydroxypropylcellulose E464, microcrystalline cellulose E460, poly(vinyl acetate-crotonic acid) copolymer, sucrose, gelatin, titanium dioxide E171, yellow iron oxide E172.

What Indocid capsules looks like and the contents of the pack

Indocid capsules are available

Indocid Capsules are supplied in packs of 90.

Indocid-R Capsules are supplied in packs of 30.

Marketing Authorisation Holder

The Marketing Authorisation is held by

Aspen Pharma Trading Ltd.

3016 Lake Drive

Citywest Business Campus

Dublin 24

Ireland

Manufacturer

Merck Manufacturing Division,

Merck Sharp & Dohme Limited,

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