

PACKAGE LEAFLET: INFORMATION FOR THE USER

Indometacin 100mg suppositories Indometacin

Read all of this leaflet carefully before you start using 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. See section 4.

In this leaflet:

1. What Indometacin suppositories are and what they are used for
2. Before you use Indometacin suppositories
3. How to use Indometacin suppositories
4. Possible side effects
5. How to store Indometacin suppositories
6. Contents of the pack and other information

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

Indometacin suppositories contain the active ingredient indometacin.

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 (disease mainly of the joints)
- Osteoarthritis (disease of the joints)
- Ankylosing spondylitis (a form of arthritis which mainly affects the back)
- Pain, inflammation, and swelling following orthopaedic surgery.
- Musculoskeletal disorders (muscles and bone disorders).
- Period pain.
- Low back pain.
- Disease of the hip joint.
- Acute gouty arthritis (a form of arthritis in which crystals build up in the joints).

2. Before you use Indometacin suppositories

Do not use Indometacin suppositories

If you are allergic to indometacin or any of the other ingredients of this medicine (listed in section 6)

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 are suffering from inflammation of the rectum causing soreness, bleeding and sometimes a discharge of mucus and/or pus from your anus.

If you have polyps (soft fleshy swellings that grow inside the nose) 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

If you are in the third trimester pregnancy or while you are breast-feeding (see Pregnancy, breast-feeding and fertility)

Warnings and precautions

Tell your doctor before using these suppositories if you:

If you are epileptic

If you have Parkinson's disease

If you have a psychiatric problem

If you have heart disease, high blood pressure or have a tendency for fluid retention

If you are being treated for infection or you have a fever

If you know you suffer from asthma, digestive tract, liver or kidney disease, diabetes or heart failure

If you have a problem with your blood clotting.

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

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

Risk of heart attack or stroke

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. 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.

Children

Not recommended for use in children.

Other medicines and Indometacin suppositories

Please tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines including:

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.

Vancomycin, a glycopeptide antibiotic.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

You must not take Indocid during the last 3 months of pregnancy. Your doctor will decide whether you can take Indocid during the first 6 months of pregnancy, it is IMPORTANT to follow your doctor's advice.

Breast-feeding

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

Female fertility

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. Withdrawal of Indocid may be considered, your doctor will decide.

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 use Indometacin suppositories

Always use Indometacin suppositories exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Suppositories must not be taken by the mouth.

They are to be placed in the rectum (back passage). Empty your bowels (if necessary) before use. Remove the suppository from the foil and, lying on your back or your side with your knees bent up, push the suppository- pointed end first - up into your back passage. Lie still for a minute or so, and then wash your hands. The suppository should remain in place and dissolve completely.

The amount you use will depend upon your condition.

Dosage:

The usual adult dosage is one suppository to be inserted into the rectum once or twice a day. One should be used at bedtime and if another is necessary it should be used in the morning.

Not recommended for use in children.

If you use more Indometacin suppositories than you should

If you use too many suppositories by mistake or someone else accidentally uses your suppositories, contact your doctor immediately or go to the nearest casualty department.

If you forget to use Indometacin suppositories

If you forget to take the suppository, 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 suppository to make up for forgotten doses.

If you stop using Indometacin suppositories

You should use Indometacin suppositories for as long as your doctor tells you to. It may be dangerous to stop using 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 experience an allergic reaction, STOP TAKING the medicine and *seek immediate medical help*:

Symptoms of allergic reactions are:

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 (lymph glands are all over the body but are noticeable in the neck and armpit when swollen as bean shaped);

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 below for liver, kidney and blood problems).

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
- Inflammation of the pancreas, symptoms may include severe upper stomach pain, often with nausea and vomiting.

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.

Other side effects include:

Problems with the central nervous system:

Headache, dizziness, light-headedness, depression, vertigo (sensation that things around you are moving) and tiredness (including feeling unwell and listlessness).

Reactions reported infrequently include anxiety, confusion, fainting, drowsiness, fits, coma, peripheral neuropathy which may be experienced as loss of sensation, numbness, tingling, and pricking sensations, sensitivity to touch, or muscle weakness, involuntary muscle movements, sleeplessness, hallucinations (seeing or hearing things that are not there), mental disorders including a loss of personal identity. Rarely, pins and needles, speech problems, worsening of epilepsy and parkinsonism symptoms (symptoms that mimic those of Parkinson's disease such as tremor or abnormal movements). If these side effects are severe you may need to stop treatment with this medicine. You should talk to your doctor.

Problems with the digestive system:

The most frequent reactions are nausea, loss of appetite, vomiting, trapped wind, constipation, and diarrhoea.

Reactions reported infrequently include inflammation of the mouth and stomach, wind, narrowing and/or obstruction of the intestines which may be seen as a swollen abdomen, and vomiting.

Liver disorders:

Rarely, inflammation of the liver and jaundice, symptoms of which may be yellowing of the eyes and skin.

Heart and kidney disorders:

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:

Infrequently, blood disorders which are usually detected in blood tests, but may be seen as pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after Injury. Blood disorders such as leucopenia and anaemia may be seen with symptoms of severe chills, mouth ulcers, headache, shortness of breath and dizziness.

Eye disorders:

Infrequently, blurred vision, double vision, pain in the eye and other visual disturbances.

Problems with the ear:

ringing in the ears and other hearing disturbances, including deafness rarely.

Other side effects:

Bleeding from the vagina in women;
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;
Flushing and sweating;
Bleeding from the nose;
Breast changes including enlargement and tenderness in men and women;
Ulcers in the lining of the mouth.

Side effects associated with the use of Indometacin suppositories

Bleeding, inflammation, burning pain, discomfort, itching or the feeling of a full back passage.

Laboratory tests

Misleading results have been seen with patients having a Dexamethasone suppression test (DST) while using this medicine.

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 the the 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 suppositories

Keep out of the reach and sight of children.

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

Do not 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. Contents of the pack and other information

What Indometacin suppositories contain

The active ingredient in Indometacin suppositories is indometacin.

Indometacin suppositories are available as polyethylene glycol suppositories containing 100mg indometacin.

Indometacin suppositories also contain: Butylhydroxyanisole, butylhydroxytoluene, edetic acid, glycerol, polyethylene glycol 8000, Macrogol 4000, purified water.

What Indometacin suppositories looks like and the contents of the pack

Indometacin suppositories are available in strips of 10

Marketing Authorisation Holder

The Marketing Authorisation is held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland Service-Tel: 0800 088 7392 (+ 44 1748 828 391)

Manufacturer

Famar S.A, 49th KM, Athens-Lamia Nat Road, 19011, Avlona, Greece.

This leaflet was last amended August 2022