

INDOCID®

Suppositories 100 mg
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, tell your doctor or pharmacist.

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1. WHAT INDOCID® IS AND WHAT IT IS USED FOR

Indomethacin is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are pain killers and reduce inflammation (redness, swelling and heat). Indocid® may be used for:

- Inflammatory diseases of the joints or surrounding arthritis, osteoarthritis of the backbone (ankylosing spondylitis)
- Muscular pain, low back pain and pain following bone or joint surgery
- Menstrual pain
- Gout.

2. BEFORE YOU TAKE INDOCID®

Do not use Indocid® if you:

- Have ever had an allergic reaction to indomethacin or any of the ingredients in the suppository. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

- Have experienced asthma attacks, allergic skin reactions (swelling, especially of the throat, or rash-es), or a runny nose while taking aspirin or any other NSAIDs or COX II inhibitors (e.g. celecoxib)
- Have haemorrhoids (piles) or inflammation or bleeding of the back passage
- Have now or have previously had stomach ulcers or bleeding in
- Have severe
- Have polyps associated with swelling difficulties in swallowing
- Are in the last three months of pregnancy
- Are giving the suppositories to a child under 12 years old. Indomethacin is NOT recommended for use in children.

If any of the above applies to you, you should NOT take Indocid®. Tell your doctor IMMEDIATELY. Medicines such as indomethacin 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. Tell your doctor if any of the above applies to you.

Check with your doctor or pharmacist before using Indocid® if you:

- Have bleeding disorders or blood clotting problems
- Suffer from a psychiatric disorder, epilepsy or parkinsonism
- Have kidney problems
- Currently have an infection (treated or not) or are receiving live vaccines
- Suffer from any condition of the liver or heart that causes fluid retention or high blood pressure
- Suffer from asthma
- Suffer from any disease of the bowel such as Crohn's disease or ulcerative colitis
- Have systemic lupus erythematosus (SLE) or other connective tissue disorders

- Are due to have an operation.

Check with your doctor or pharmacist if you are taking any of the following:

- Aspirin or related medicines (salicylates)
- Other NSAIDs including diflunisal
- Quinolone antibiotics (such as ciprofloxacin)
- SSRI antidepressants (e.g. paroxetine)
- Sulphonylureas (used to treat diabetes)
- Medicines used to treat high blood pressure (such as atenolol, captopril, doxazosin, hydralazine, losartan, nifedipine, propranolol or quinipril)
- Anti-platelet medicine or drugs to stop the blood clotting
- Lithium or haloperidol (psychiatric medicines)
- Anti-viral medicines (such as zidovudine or ritonavir)
- Cardiac glycosides (used to treat heart conditions e.g. digoxin)
- Ciclosporin or tacrolimus (immune system medicine)
- Corticosteroids (anti-inflammatory)
- Methotrexate (used to treat some cancers, severe psoriasis and severe rheumatoid arthritis)
- Desmopressin (hormone preparation used for night-time bed wetting)
- Thiazides, furosemide and triamterene (control fluid levels in the body)
- Mifepristone (used to induce abortion)
- Baclofen (muscle relaxant)
- Pentoxifylline (used to treat vascular disease)
- Probenecid (a treatment for gout)
- Tiludronic acid (used to treat bone diseases)
- Phenylpropanolamine (nasal decongestant).

Pregnancy and 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.

If you are pregnant or are breast-feeding speak to your doctor or pharmacist before taking this medicine.

Driving and using machines:

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

Other precautions you should take:

Indocid® may alter the results of some blood or urine tests. If you see another doctor or go into hospital, let them know what medicines you are taking.

3. HOW TO TAKE INDOCID®

Your doctor has decided the dose which is best for you. Always follow your doctor's instructions exactly.

If you do not understand anything, ask your doctor or pharmacist.

The usual dosage(s) are described below:

Adults: One suppository to be inserted into your back passage (rectum) at night and repeated in the morning if necessary.

Elderly: Your doctor may prescribe you a different dose and monitor your progress more closely.

Children: Not recommended.

These suppositories should be used as instructed and inserted into the back passage, they must not be swallowed.

If you use more Indocid® than you should:

Do not insert more suppositories than your doctor tells you to. If you insert more than the stated dose or you or a child accidentally swallows a suppository, go to the nearest hospital casualty department or tell your doctor immediately. If an overdose has been taken, there may be signs such as headache, feeling or being sick, stomach pain or bleeding, drowsiness, dizziness, ringing in the ears or fainting.

If you forget to use Indocid®:

If you forget to use a suppository, use another as soon as you remember unless it is nearly time to use the next one. Never insert two suppositories at the same time. Use the remaining doses at the correct time.

4. POSSIBLE SIDE EFFECTS

Like many medicines, Indocid® may occasionally cause side effects in some patients, particularly when you first start taking it. These may include effects on the nervous system such as headache and dizziness. If you get a prolonged headache, tell your doctor. If you develop a rash or become jaundiced (yellow skin or eyes) stop taking indomethacin and talk to your doctor immediately.

Aseptic meningitis can occur in some patients.

This may show as a combination of symptoms such as headache, fever, stiff neck, tiredness, feeling ill and your eyes become very sensitive to bright light.

If you experience any of these symptoms seek medical attention immediately. Medicines such as indomethacin may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you suffer from any of the following at any time during your treatment stop using the medicine and seek immediate medical help: pass blood in your faeces, pass black tarry stools or vomit blood or dark particles that look like coffee grounds.

Stop using the medicine and tell your doctor if you experience: indigestion or heartburn, abdominal pains (pains in your stomach) or other abdominal symptoms.

Other side effects are:

- Effects on the blood changes in the numbers and types of blood cells. If you develop bruising, sore throats, nose bleeds or infections tell your doctor who may wish to test your blood.
- Allergic reactions skin rash which may be itchy, itching, redness, swelling especially of the throat, difficulty breathing, asthma and fluid in the lungs.
- Effects on the nervous system fatigue, drowsiness, dizziness, headache, problems with speech, fainting, nervousness, coma, lightheadedness, vertigo, tiredness, hallucinations (seeing things that are not there), difficulty sleeping, depression, confusion, anxiety, mental disturbances, involuntary movements, loss of coordination, numbness and tingling, fits or worsening of fits and parkinson's syndrome

- Effects on the eye - pain in and around the eye, blurred or double vision, inflammation of the optic nerve, deposits in the front surface of the eye (cornea) or effects on the back surface of the eye (retina).
- Effects on the ears - ringing or buzzing or other hearing disturbances (rarely deafness).
- Effects on the heart - swelling especially of ankles, high or low blood pressure, chest pain, fast or irregular heartbeats and heart failure.
- Effects on the stomach - feeling or being sick, abdominal pain or discomfort, loss of appetite, con-

stipation or diarrhoea, flatulence, inflammation of the mouth or guts or worsening of these conditions and ulceration of the intestines which can cause

- perforate (burst), worsen Crohn's disease or ulcerative colitis.
- on the liver inflammation, jaundice (yellow skin or eyes).

- Effects on the skin sensitivity to light, worsening of psoriasis.
- Effects on the kidney - inflammation, disease or failure, blood or protein in the urine and increase in blood urea.
- Other effects increase in blood sugar, sugar in the urine, high blood potassium, bleeding from the vagina, breast changes (enlargement, tenderness, breast development in men), flushing, sweating, muscle weakness, worsening of cartilage damage and mouth ulcers.
- Effects associated with the use of Indocid® bleeding, inflammation, burning pain, discomfort, itching or the feeling of a full back passage.

Tell your doctor if you notice or are worried by any of the side effects listed or notice any other effects not listed. If you get any other unusual effects, tell your doctor or pharmacist immediately and seek advice.

5. HOW TO STORE INDOCID®

- Do not use Indocid® suppositories after the expiry date stated on the carton and the strips. The expiry date refers to the last day of that month.
- Keep the suppositories stored in a cool place.
- Do not transfer them to another container.
- Do not store above 30°C.

• Keep out of reach and sight of children.

- Return all unused medicines to your pharmacist for safe disposal.

6. Further information

What Indocid® contains:

Indocid® 100 mg suppositories contains 100 mg indomethacin.

Excipients: Polyethylene glycol, carbowax, butylated hydroxyanisole, glycerin, ethylenediamine tetraacetic and butylated hydroxytoluene.

What Indocid® looks like and content of the pack

Indocid® suppositories are off-white. Indocid® is supplied in packages of 10 suppositories.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

For more information about this medicinal product, please contact:

Algorithm SAL
Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries
Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgx.net
Website: www.algorithm-lb.com

Also contact the relevant competent authority.

- This is a medicament**
A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
The doctor and the pharmacist are experts in medicine, its benefits and risks.
Do not by yourself interrupt the period of treatment prescribed.
Do not repeat the same prescription without consulting your doctor.

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