

PACKAGE LEAFLET: Information for the user

INDOMETACINE

Suppositories – 100 mg

(Indomethacin)

Read all of this leaflet carefully before you start using 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 effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Indometacine is and what it is used for
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1. WHAT INDOMETACINE IS AND WHAT IT IS USED FOR

Indomethacin belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These drugs are soothing pain medications and reduce swelling (inflammation) with all its signs.

Indometacine suppositories can be used for:

- inflammatory diseases of the joints or surrounding tissues such as rheumatoid arthritis, osteoarthritis and degenerative diseases of the coxo-femoral joint;
- deformation and stiffness of spinal cord (ankylosing spondylitis);
- muscle pain, back pain and pain coming from the bones;

- menstrual pain;
- gout.

Your doctor may have given Indometacine for another purpose. Ask your doctor if you want to know why you have been given Indometacine.

2. BEFORE YOU USE INDOMETACINE

Do not use Indometacine if:

- you are allergic to indomethacin or to any of the other ingredients of the suppositories;
- you have experienced hypersensitivity reactions like: asthma attack, allergic skin reaction which looks like rash, swelling of the throat or rhinitis (runny nose), angioedema, urticaria during the time you have used aspirin or another non-steroidal anti-inflammatory medicine;
- you suffer from haemorrhoids, inflammation and bleeding of the rectum;
- you suffer or have suffered before from peptic ulcer (ulcer in the stomach or duodenum) or bleeding from your gastrointestinal tract;
- you have severe lung, renal, or heart diseases;
- you suffer from nasal polyps;
- you are in the last trimester of pregnancy;
- the patient is a child under 14 years old.

If you think you have any of the conditions mentioned above, do not use Indometacine, first consult with your doctor and follow the advice given.

Take special care with Indometacine

Inform your doctor if:

- you have bleeding disorders or blood clotting problems;
- you suffer from psychiatric disorders, epilepsy or parkinsonism;
- you have renal diseases;
- you suffer from liver diseases;
- you have an infection (treated or not) or if you have taken vaccine;
- you suffer from lung or heart conditions that cause fluid retention or high blood pressure;

- you suffer from asthma;
- you suffer from any intestinal diseases like Crohn's disease or ulcerative colitis;
- you have systemic lupus erythematosus (SLE) or any other tissue disorder associated with the former;
- you are obliged to have an operation;
- you notice any change in your vision during the time you use the drug (your doctor must examine your eyes at intervals during long-term treatment with indomethacin);
- you experience headache, accompanied by dizziness, at the beginning of the treatment; starting therapy with a lower dose and increasing it gradually, reduces the incidence of headache. These symptoms frequently disappear on continuing therapy or with reduction of the dose, but if headache persists despite the reduction of the dose, you should withdraw the drug.

Medicines such as Indometacine may be associated with a small increased risk of myocardial infarction or stroke.

The risk increases with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. You might be at risk if you are in these conditions: you have high blood pressure, diabetes or high cholesterol or are a smoker.

Care should be done when used in elderly because they have a higher risk of getting side effects, especially in the gastrointestinal tract, which may be fatal. Your doctor should therefore prescribe the lowest dose that gives you sufficient relief. If you experience any unusual symptoms in the stomach or intestine, you must tell your doctor about it.

Taking other medicines

Inform your doctor or pharmacist if you are using or have recently used other medicines, even those without a prescription because:

- when indomethacin is used concomitantly with: ethanol, alendronate, glucocorticoids, salicylates, or other anti-inflammatory drugs, the risk of gastrointestinal toxicity increases;
- additive effects can be observed when given together with anti-platelets, anticoagulants or thrombolytics;
- concomitant use with cidofovir is contraindicated due to increased nephrotoxicity;
- indomethacin increases the plasmatic concentration of aminoglycosides in premature infants;

- indomethacin may increase the plasmatic concentration of lithium and digoxin;
- the plasmatic concentrations of indomethacin increase when it is given together with probenecid;
- indomethacin may increase the nephrotoxicity of cyclosporine;
- the concomitant use with diuretics (mainly triamterene) may increase nephrotoxicity;
- indomethacin may strengthen the hypoglycemic effect of antidiabetics;
- indomethacin may reduce the hypotensive effect of the angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin II receptor antagonists;
- indomethacin inhibits the glucuronidation of zidovudine;
- a higher risk for convulsions exists when indomethacin is taken concomitantly with quinolone antibiotics;
- nonsteroidal anti-inflammators reduce renal elimination of methotrexate;
- indomethacin may reduce the effect of beta-blockers;
- the efficacy of mifepristone may be reduced when taken concomitantly with indometacin.

Concomitant administration of indomethacin with selective serotonin reuptake inhibitors may increase the risk of gastrointestinal bleeding, while concomitant treatment with tacrolimus may increase the risk for nephrotoxicity.

Pregnancy

Indometacine suppositories may harm the ability to get pregnant. Tell your doctor or pharmacist if you are pregnant, are planning to get pregnant or if you have difficulties in getting pregnant. If you are pregnant, consult your doctor or pharmacist before using this medicine.

This drug is contraindicated during the third trimester.

Breastfeeding

If you breastfeed your baby, you should consult your doctor or pharmacist before using the drug.

Driving and using machines

Indometacine may cause: headache, drowsiness, dizziness, blurred vision.

For this reason it is not recommended to drive and use machinery under the effect of this drug.

3. HOW TO USE INDOMETACINE

Always indomethacine is used exactly as your doctor or pharmacist advised you.

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

Dosage:

Adults: One suppository (100 mg) is inserted at night through rectal route, and if it is necessary, this action is repeated in the next morning.

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

Children: Not recommended.

These suppositories should be used according to the instructions and should be taken through rectal route. MUST NOT be swallowed.

If you use more Indometacine than you should

Do not use more Indometacine than your doctor's recommendation.

If you have used a higher dose than the prescribed one, or if your child has swallowed a suppository, contact the nearest hospital or contact your doctor immediately. If you have taken an overdose, signs such as: headache, feeling or being sick, stomach pain or bleeding, lethargy, swelling, tinnitus or weakness may appear.

If you forget to use Indometacine

If you forget to use a dose, use it as soon as you remember, except the case the time to use the next dose has come. NEVER use two suppositories at the same time. Use the doses at the right time.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Inform your doctor if any of the following side effects bothers you:

- side effects in the nervous system: headache, dizziness, weakness, somnolence, speech disorders, tiredness, nervousness, convulsions, syncope, psychiatric disorders, confusion, depression, coma;

- indigestion and heartburn, abdominal pain (stomach pain) or other abdominal symptoms such as: nausea, vomiting, diarrhoea, constipation, inflammatory bowel disease, liver function disorders;
- rash, jaundice (yellowing of the skin and eyes), sensitivity to light, worsening of psoriasis, toxic epidermal necrolysis or Stevens - Johnson syndrome (severe skin reactions), alopecia (hair loss);
- have a combination of symptoms such as headache, neck stiffness, fatigue, feeling or being sick, and your eyes become more sensitive to sunlight;
- corneal deposits, vision disorders;
- blood effects, changes in the number and types of blood cells such as: agranulocytosis, haemolytic anaemia, leucopenia, thrombocytopenia, anaemia secondary to gastro-intestinal haemorrhage;
- bone marrow disorders;
- heart failure, vasculitis (inflammation of the blood vessels);
- hearing impairment;
- bruising, irritated throat, nasal bleeding or infections;
- allergic reactions: rash that causes itching and redness, especially swelling of the throat, difficulty in breathing, asthma and fluid in the lungs, lungs inflammation;
- effects in the kidney: inflammation, disease or renal failure, blood or proteins in urine and increased concentration of blood urea;
- increased level of sugar in the blood, sugar in urine, high levels of potassium in the blood, bleeding from the vagina, breast changes (enlargement, sensitivity, breast development in men), redness, sweating, muscular weakness, worsening of the injuries of cartilages, ulcers in the mouth;
- effects associated with the use of suppositories, such as: bleeding, inflammation, malaise, itching, feeling of a full back passage.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INDOMETACINE

Keep out of the reach and sight of children.

Do not use Indometacine after the expiry date stated on the package.

Store at a temperature lower than 25°C.

Protect the drug from light and humidity.

6. FURTHER INFORMATION

What Indometacine 100 mg suppositories contain

The active substance is indomethacin.

Each suppository contains 100 mg of indomethacin.

The excipients are: colloidal anhydrous silica, hard fat.

Packaging content

Box with 10 suppositories.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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