

PACKAGE LEAFLET: INFORMATION FOR THE USER

Indometacin Aurobindo 25 mg, capsules Indometacin Aurobindo 50 mg, capsules

indometacin

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please ask your doctor or pharmacist.
Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
Do you experience any side effects not listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Please contact your doctor or pharmacist.

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1. WHAT IS INDOMETACIN AUROBINDO AND WHAT IS IT USED FOR?

Indometacin belongs to the group of non-hormonal anti-inflammatory painkillers (so-called NSAIDs or prostaglandin synthesis inhibitors). It has analgesic, anti-inflammatory, and antipyretic properties.

Indometacin Aurobindo 25 mg and 50 mg is used in the treatment of:

- rheumatic-like inflammations of the joints (also in young age)
- acute inflammatory conditions of the muscles and joints, e.g., tendon or bursitis
- osteoarthritis ("worn" joints/hip)
- sudden gout attacks
- acute or chronic lower back pain (lumbago)
- ankylosing spondylitis (certain stiffening and curvature of the spine)
- severe menstrual pains
- pain and swelling after surgical procedures, in dislocation or in bone fractures.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS WITH IT?

When should you not use this medicine?

Indometacin Aurobindo 25 mg and 50 mg should not be used by patients who:

- are allergic to indometacin or any of the substances contained in this medicine. You can find these substances under section 6
- are in the last phase of pregnancy

- previously experienced itching, acute rhinitis (runny nose), or asthma-like attacks after taking acetylsalicylic acid or other prostaglandin synthesis inhibitors
- previously experienced gastrointestinal bleeding after taking prostaglandin synthesis inhibitors
- have a (recurrent) stomach ulcer or bleeding of the gastrointestinal tract
- have (had) gastrointestinal bleeding or other bleedings, such as a cerebral hemorrhage
- suffer from severe heart failure.

When should you be extra careful with this medicine?

This medicine should be used with caution by patients with:

- gastrointestinal complaints or who have ever suffered from them. If you have previously suffered from damage to the gastrointestinal tract, you should report any symptoms indicating abnormalities in the gastrointestinal tract (especially bleeding), particularly at the start of treatment. Damage to the gastrointestinal tract is more common in the elderly and can also occur without having had such complaints before. If severe gastrointestinal issues occur during the use of indomethacin, you should stop using it. Indomethacin can mask the symptoms of a stomach ulcer. (see also under “When should you not use this medicine?”)
- psychiatric disorders, epilepsy, or Parkinson's disease; these conditions may sometimes worsen with the use of indomethacin
- heart conditions, high blood pressure, or other conditions where fluid retention may occur
- blood clotting disorders; have the thrombosis service or doctor regularly check the blood clotting
- impaired kidney function; especially with long-term treatment, kidney function should be regularly monitored
- impaired liver function, with diabetes, with “blood poisoning” or with signs of dehydration.

Patients of advanced age have an increased risk of side effects. In children, liver function should be regularly determined by the doctor.

Medicines like Indometacine Aurobindo may be associated with a slightly increased risk of a heart attack (“myocardial infarction”) or stroke. Do not take more than the prescribed dose and do not use the medicine longer than the prescribed treatment. The risk increases with higher doses and longer use of the medicine.

If you have heart problems, have had a stroke, or if you think you are at risk for these (for example, if you have high blood pressure, diabetes, high cholesterol, or if you smoke), you should discuss this with your doctor or pharmacist before taking this medicine.

Indomethacin, due to its anti-inflammatory effect, like other prostaglandin synthetase inhibitors, can mask the symptoms of infections and gastrointestinal ulcers.

It is recommended to have periodic eye examinations. If blurred vision occurs as a side effect, a doctor should be consulted immediately.

In patients with persistent headaches that continue even after dose reduction, therapy should be discontinued.

Long-term use of indomethacin can lead to headaches. In such cases, you should contact your doctor, as discontinuation of the medicine may be necessary.

Are you using any other medicines?

Are you using any other medicines besides Indometacine Aurobindo, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

An interaction may occur with the use of this medicine with:

- adrenal cortex hormones (corticosteroids); the risk of gastrointestinal ulcers and bleeding is increased
- anticoagulants; the effect of the anticoagulants may be enhanced
- platelet aggregation inhibitors and selective serotonin reuptake inhibitors (SSRIs); the risk of gastrointestinal ulcers and bleeding is increased
- other anti-inflammatory, pain-relieving drugs from the NSAID group (e.g., ibuprofen, acetylsalicylic acid); these should not be combined with indomethacin
- lithium (for depression)
- methotrexate (a chemotherapy drug); the side effects of methotrexate are exacerbated
- diuretics and antihypertensive drugs; the effect of these drugs may be reduced; triamterene (potassium-sparing diuretic) should not be used in combination with indomethacin
- digoxin (for, among others, heart failure)
- ciclosporin (for, among others, transplants) and zidovudine (for AIDS); the side effects of these drugs may be exacerbated
- probenecid (for, among others, gout); this enhances the effect, requiring a lower dose of indomethacin.

If you are using one or more of these drugs, it is advisable to first seek advice from your doctor or pharmacist.

Pregnancy and breastfeeding

Do not use this medicine in the last three months of pregnancy; it can harm your unborn child or cause problems during delivery. Your unborn child may experience kidney and heart problems. The medicine can affect your and your baby's susceptibility to bleeding and cause the delivery to occur later or last longer than expected. Do not use this medicine during the first six months of pregnancy unless absolutely necessary and recommended by your doctor. If you need to be treated during this period or while trying to become pregnant, the lowest dose should be used, and the treatment should be kept as short as possible. From week 20 of pregnancy, if this medicine is used for more than a few days, it can cause your unborn child to develop kidney problems, which may result in too little amniotic fluid around the child (oligohydramnios) or narrowing of a blood vessel in your baby's heart (ductus arteriosus). If you need to be treated for more than a few days, your doctor may recommend additional monitoring.

Indomethacin is excreted in breast milk. Indomethacin Aurobindo should not be used during breastfeeding.

Driving and using machines

If you experience symptoms such as dizziness, your reaction time may be impaired. You should not drive a motor vehicle or perform hazardous tasks that require alertness.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The usual dosage is as follows:

Adults

In chronic rheumatic conditions, treatment should start with a low dose, which the doctor can gradually increase if necessary. The therapy should be continued for a sufficient duration (recommended up to 1 month).

The dosage usually ranges from 50 to 200 mg per day, divided into several doses.

In case of persistent nocturnal pain or morning stiffness, a dose of 100 mg before bedtime may be prescribed.

In elderly patients or those with impaired liver or kidney function, the doctor should prescribe a lower dosage.

Acute gout attack

The dosage is 150 to 200 mg per day until all symptoms have disappeared.

Menstrual pain

The recommended dosage is 75 mg per day in one or more doses. Treatment should begin at the onset of cramps or bleeding and continue as long as symptoms are present.

Children from 16 years (or lighter than 50 kg)

The initial dosage for children is 1 mg/kg body weight per day divided into 2 or 3 doses.

If necessary, the doctor will gradually increase the dosage to a maximum of 2 mg/kg body weight per day. Upon improvement, the doctor should reduce the dosage to the lowest possible level or discontinue the treatment.

When and how should the capsules be taken?

The capsules are best taken with some milk, food, or in combination with an antacid. This reduces the risk of gastrointestinal complaints.

How long can the medication be used?

This medication can be used for a short or long period, depending on the condition. Refer to the relevant section under "How to use this medication?".

Have you used too much of this medication?

If you suspect a severe overdose, you should immediately contact a doctor. Symptoms may include nausea, vomiting, diarrhea, severe headache, dizziness, confusion, prolonged unconsciousness, or coma.

Have you forgotten to use this medication?

Take the dose as soon as you realize you forgot to take it, unless you only discover it when it's time for your next dose. In that case, do not take the missed dose extra but continue with your schedule.

If you stop using this medication

When using Indometacin Aurobindo for gout attacks, you should not stop using it suddenly, as the gout attacks may return.

In case of bleeding from the stomach or intestines, eye abnormalities, hypersensitivity reactions, liver function disorders, or persistent headache, you should always stop using it immediately and consult your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

What side effects are known?

The following side effects may occur, among others:

- headache, dizziness, light-headedness (especially at the start of treatment, see also under "What else should you pay attention to?")
- depression, fatigue, lethargy
- stomach and intestinal complaints (such as nausea, (bloody) vomiting, abdominal pain, diarrhea or constipation, flatulence, stomach or (esophageal) ulcers, gastrointestinal bleeding (recognizable by black, very foul-smelling stools), indigestion, loss of appetite, inflammation in the mouth), worsening of colitis and Crohn's disease
- vaginal bleeding, sweating, hot flashes
- tinnitus, reduced hearing.

Less common are:

- confusion, anxiety, mental disorders, drowsiness or insomnia
- seizures, unconsciousness, fainting
- muscle weakness, involuntary muscle contractions, cramps, feeling "like ants are crawling over the skin"
- inflammation in the stomach
- fluid retention, increased or decreased blood pressure, palpitations, rapid heartbeat, chest pain, heart weakness, heart failure
- hypersensitivity reactions, such as itching, hives, (sometimes severe) skin rash, hair loss, sudden shortness of breath, asthma, rapid drop in blood pressure, swelling in the face and mucous membranes
- reduced number of blood cells, anemia, skin bleeding, bruising, redness.

Rarely reported are:

- jaundice, hepatitis
- reduced vision, double vision, pain in or around the eye sockets, abnormalities of the cornea or retina
- disorders of kidney function (blood or protein loss in the urine, inflammation of the renal medulla).

Medicines like Indometacine Aurobindo may be associated with a slight increased risk of a heart attack (“myocardial infarction”) or stroke.

If you experience bleeding from the stomach or intestines, eye abnormalities, skin rash, or breathing problems, you should stop using it and consult your doctor.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Store below 25°C, in the tightly closed packaging.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the packaging after “Do not use after:” and on the strip after “Exp.:”. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is indometacin. Indometacine Aurobindo 25 mg and 50 mg contain per capsule 25 mg and 50 mg indometacin, respectively.

The other substances in this medicine are corn starch, cellulose, colloidal silicon dioxide, magnesium stearate. The capsule itself consists of gelatin, iron oxide (E172), and titanium dioxide (E171). The printing ink contains a very small amount of shellac and black iron oxide (E172) and propylene glycol.

What does Indometacine Aurobindo look like and what is in a package?

The 25 mg and 50 mg capsules are light yellow, with black print respectively “C” and “25 mg” or “C” and “50 mg”.

The capsules are packed in blister strips of 10 pieces in a cardboard box of 30 pieces or in polypropylene bottles.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aurobindo Pharma BV, Baarnsche Dijk 1, 3741 LN Baarn

Manufacturers:

Aurobindo Pharma BV, Baarnsche Dijk 1, 3741 LN Baarn
Generis-Farmaceutica, S.A., Rua Joao de Deus, n° 19, 2700-487, Venda Nova, Amadora, Portugal
The capsules are registered under RVG 21813 (25 mg) and RVG 21814 (50 mg).

This leaflet was last approved in December 2022.

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