

Package leaflet: information for the user

Indometacin suppository CF 50 mg, suppositories Indometacin suppository CF 100 mg, suppositories

indometacin

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

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1. What is Indometacin suppository CF and what is it used for?

Action

Indometacin has anti-inflammatory, analgesic, and antipyretic effects. These effects are achieved in the body by inhibiting prostaglandin synthetase. Indometacin is rapidly absorbed in the body.

To be used for

- rheumatoid arthritis
- joint wear, wear of the hip joint
- rheumatic-like inflammations of the spinal joints that eventually lead to ossification and stiffening of the spine
- gout or an acute attack of gout
- acute conditions of the musculoskeletal system such as bursitis, tendonitis, inflammation of the tendon sheath, or inflammation of the joint capsules
- lumbago and inflammation after surgical procedures such as setting a bone fracture or fixing it, if this inflammation is not the result of a bacterial infection
- severe menstrual pain.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

- In the third trimester of pregnancy.
- In case of an acute asthma attack, hives, or nasal mucosa inflammation as a result of using acetylsalicylic acid or similar agents in the medical history.
- If you have or have had active or recurrent lesions of the gastrointestinal tract, gastrointestinal bleeding, or brain bleeding.
- If you have or have had inflammations of the rectum or a recent rectal bleeding.
- In case of severe heart failure.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- Medicines like Indometacine CF 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.
- Concurrent use of Indometacine CF and other pain-relieving, anti-inflammatory, fever-reducing agents (so-called NSAIDs, including 'COX-2 inhibitors', a part of this group of medicines) should be avoided.
- Your doctor will prescribe the lowest effective dose for the shortest possible period to minimize the chance of side effects.
- Older patients have a higher risk of experiencing side effects.
- Indomethacin should not be used in children under 2 years of age. Children over 2 years should be closely monitored during treatment with indomethacin.
- Liver toxicity can occur, and this should be monitored by determining liver function.
- Headache, sometimes with dizziness or a light-headed feeling, can occur especially at the beginning of treatment. If these symptoms persist, it may be a reason to discontinue treatment with indomethacin.
- Caution is advised in patients suffering from psychiatric disorders, such as epilepsy and Parkinson's disease.
- If severe gastrointestinal complaints occur (including bleeding), the use of indomethacin should be discontinued.
- Patients who have previously experienced gastrointestinal toxicity, especially the elderly, should report any symptoms indicating gastrointestinal abnormalities (especially bleeding) (see also 'Do not use Indomethacin suppository CF'), especially at the start of treatment.
- Caution is advised in patients who are simultaneously treated with medications that can increase the risk of ulceration and bleeding, such as corticosteroids with anti-inflammatory effects, anticoagulants like warfarin, some antidepressants (SSRIs), and medications that inhibit blood clotting like acetylsalicylic acid.
- In patients suffering from heart dysfunctions, high blood pressure, or conditions leading to fluid retention, indomethacin may increase the risk of fluid accumulation in the body.
- Indomethacin can mask the symptoms of an infectious disease. Your doctor should be aware of this if they need to treat you for an infection while you are using indomethacin.
- Indomethacin can lead to eye abnormalities, manifesting as blurred vision. If you have poor vision, an eye examination is justified. Regular eye examinations are advisable during long-term treatment with indomethacin.

- Indomethacin inhibits blood clotting. In patients with blood clotting disorders, indomethacin should be used with great caution. In rare cases, blood count abnormalities may also occur.
- In patients with impaired kidney function, indomethacin can lead to further deterioration of this kidney function. Risk factors include known kidney or liver dysfunctions, diabetes, heart failure, sepsis, or the use of medications that can be toxic to the kidney. Impaired kidney function can lead to an excessive amount of potassium in the blood, which can cause dangerous heart rhythm disturbances.
- Indomethacin can make it difficult to become pregnant. Inform your doctor if you wish to become pregnant or if you have problems becoming pregnant while using this medication.
- Severe skin reactions, some of which are fatal, including skin inflammation with large peeling (exfoliative dermatitis), severe hypersensitivity reactions with (high) fever, red spots on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), and death of the upper layer of the skin (epidermal necrolysis) have been very rarely reported in association with the use of NSAIDs (see 'Possible side effects'). Patients appear to be at greatest risk for these reactions at the start of treatment (in the first month). Treatment with Indomethacin CF should be stopped at the first signs of skin rash, mucous membrane lesions, or any other signs of hypersensitivity.
- Due to the use of suppositories, irritation of the anus may occur. This may be accompanied by a feeling of urgency to defecate (see also section 4).

Are you using any other medications?

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

Medications can sometimes interact with each other. An interaction means that medications can influence each other's effects and/or side effects when used simultaneously.

Simultaneous use of indomethacin and the following agents can increase the risk of side effects:

- other so-called prostaglandin synthetase inhibitors (e.g., acetylsalicylic acid).
- Concurrent use of acetylsalicylic acid and indomethacin increases the risk of gastrointestinal side effects and decreases the levels of indomethacin in the blood.
- diflunisal (for the treatment of pain and inflammation). Concurrent use of diflunisal and indomethacin increases the risk of gastric bleeding and the amount of indomethacin in the blood.
- zidovudine (for the treatment of AIDS). Concurrent use of zidovudine and indomethacin leads to a higher risk of blood count abnormalities.
- phenylpropanolamine (a drug for airway spasms and for the treatment of shock). Concurrent use of phenylpropanolamine and indomethacin can lead to a sudden rise in blood pressure to harmful levels.
- adrenal cortex hormones (corticosteroids) with, among others, an anti-inflammatory effect.
- Concurrent use of adrenal cortex hormones and indomethacin can lead to an increased risk of ulcer formation and bleeding in the gastrointestinal tract.
- medicines that prevent blood clotting and antidepressants (SSRIs) (see also 'Be extra careful with Indometacine suppository CF'). Concurrent use of these medicines and

indomethacin can cause an increased risk of ulcer formation and bleeding in the gastrointestinal tract.

- ciclosporin (a drug that suppresses immune reactions after a transplant). Concurrent use of ciclosporin and indomethacin increases the side effects and toxicity of ciclosporin.

The following drug can affect the action of indomethacin:

- probenecid (for the treatment of gout). Concurrent use of probenecid and indomethacin leads to an increase in the amount of indomethacin in the blood.

Indomethacin can affect the action of the following drugs:

- methotrexate (a drug used, among other things, in the treatment of certain tumors). Concurrent use of methotrexate and indomethacin can slow the rate at which methotrexate is eliminated from the body.
- lithium (a drug for a so-called manic-depressive disorder). The rate at which lithium is eliminated from the body decreases, and therefore blood levels should be regularly monitored.
- diuretics. Concurrent use of diuretics and indomethacin can reduce the effect of the diuretics. This combination can also be more harmful to the kidneys than either drug alone.
- digoxin (a drug that strengthens the heart's pumping power and promotes a regular heartbeat). Concurrent use of digoxin and indomethacin can slow the rate at which digoxin is eliminated from the body. An adjustment of the digoxin dosage may be necessary.
- antihypertensive drugs. Concurrent use of antihypertensive drugs and indomethacin can reduce the effect of the antihypertensive drugs. Blood pressure measurement may be advisable in such cases.
- the so-called dexamethasone suppression test (used to determine adrenal function). Indomethacin can negatively affect the outcome of the test.
- anticoagulants. Concurrent use of anticoagulants and indomethacin can slow blood clotting. It is advisable to regularly monitor blood clotting in such cases.

### Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

### Pregnancy

Do not use this medicine in the last three months of pregnancy; it may harm your unborn child or cause problems during delivery. Your unborn child may experience kidney and heart problems. The medicine may 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, this medicine – if used for more than a few days – can cause your unborn child to develop kidney problems, which may result in the child having too little amniotic fluid around it (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.

#### Breastfeeding

Indomethacin is excreted in breast milk. Use during the breastfeeding period is not recommended.

#### Driving and using machines

Indomethacin can cause dizziness. You should take this into account when driving motor vehicles or operating machinery.

### 3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

#### Dosage

The recommended dosage is 50 to 200 mg of indomethacin per day in divided doses. The dosage can be adjusted based on your response to the medicine and the occurrence of side effects. A single "loading dose" is not necessary when administering indomethacin.

#### Dosage for rheumatism or rheumatic conditions:

The initial dosage is 25 mg 2 to 3 times daily. This dosage can be gradually increased based on the effect and the occurrence of side effects. To determine the effectiveness of the treatment, it will be continued for at least 1 month.

#### Dosage for nighttime pain or morning stiffness:

The dosage is a maximum of 100 mg, to be used before bedtime. The maximum daily dose is 200 mg.

#### Dosage for an acute gout attack:

The recommended dosage is 150 to 200 mg per day divided into several doses, until all symptoms have disappeared.

#### Dosage for severe menstrual pain:

The recommended dosage is 75 mg per day, either in one dose or divided into several doses, starting at the onset of cramps or bleeding and continuing as long as the symptoms usually last.

#### Method of use

Gently insert the suppositories into the anus. You may moisten the tip of the suppository with some water if necessary.

#### Have you used too much of this medicine?

The most noticeable symptoms of overdose are: nausea, vomiting, diarrhea, severe headache, confusion, loss of sense of direction and place, lethargy, and even coma. Sometimes a stomach bleed may occur. If you suspect an overdose or notice it, you should immediately contact a doctor. Show him the packaging or the patient leaflet. He can then treat you further in the correct way.

Have you forgotten to use this medicine?

If you have forgotten to use your indomethacin suppository, you should still do so. If the time until the next dose is relatively short, it is better to skip the next dose and then continue the treatment according to your doctor's prescription. Never take 2 doses in quick succession. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

If you wish to stop using indomethacin, it is best to do so in consultation with your doctor. The doctor will indicate how you can best taper off the use of indomethacin.

Usually, the dosage will be gradually reduced until you eventually no longer use indomethacin.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

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

Medicines such as Indomethacin suppository CF may be associated with a slightly increased risk of a heart attack ("myocardial infarction") or stroke.

The following other side effects have been reported. For most side effects, it cannot be determined from the available data how many users experience them, unless explicitly stated otherwise.

##### Blood and lymphatic system disorders

- changes in blood count, including blood disorder (lack of white blood cells) associated with increased susceptibility to infections (leukopenia), anemia due to disease or damage to the bone marrow (aplastic anemia), anemia due to excessive breakdown of blood (hemolytic anemia), blood disorder (lack of platelets) associated with bruising and bleeding tendency (thrombocytopenia), clotting problems (disseminated intravascular coagulation)
- anemia due to gastrointestinal bleeding
- small pinpoint skin hemorrhages (petechiae), bruises (ecchymosis), hemorrhages (purpura)
- rare (in 1 to 10 out of 10,000 users): very severe blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis), bone marrow damage (a clear link with indomethacin is not established).

##### Nervous system disorders

- headache
- dizziness, lightheadedness, balance disorder (vertigo)
- (severe) depression, anxiety, confusion
- fatigue, feeling unwell (malaise), lethargy
- fainting (syncope)
- drowsiness, insomnia
- seizures/convulsions

- coma
- non-inflammatory disorders of the nervous system including muscle weakness in the arms and legs (peripheral neuropathy), muscle weakness, involuntary muscle movements
- mental disorders such as detachment from oneself or one's own feelings (depersonalization), periods of severe mental illness where control over one's own behavior and actions is disturbed (psychotic episodes)
- rare (in 1 to 10 out of 10,000 users): experiencing tingling, itching, or tingling without cause (paresthesia), speech disorders (dysarthria), worsening of epilepsy and symptoms resembling Parkinson's disease (parkinsonism). The severity of this may sometimes necessitate discontinuation of therapy.

#### Eye disorders

- visual disturbances, double vision
- pain in and around the eye socket (orbital and periorbital pain)
- corneal clouding
- retinal abnormalities, including macular abnormalities (the part that transmits images to the brain).

#### Balance and ear disorders

- tinnitus (ringing in the ears)
- hearing disorders
- rare (in 1 to 10 out of 10,000 users): deafness.

#### Cardiac disorders and vascular disorders

- fluid retention (edema), increased blood pressure (hypertension), accelerated heart rate (tachycardia), chest pain, vasodilation, arrhythmias, palpitations, decreased blood pressure (hypotension), heart failure (insufficient pumping power of the heart) (decompensatio cordis).

#### Gastrointestinal disorders

- nausea, loss of appetite (anorexia), vomiting, dyspepsia with symptoms of fullness in the upper abdomen, stomach pain, belching, nausea, vomiting, and heartburn, abdominal pain, diarrhea, constipation
- formation of ulcers (ulceration) in the esophagus, stomach, duodenum, small or large intestine, possibly with perforation of the stomach or intestinal wall and bleeding, with some rare cases resulting in death; gastrointestinal bleeding or large intestine bleeding without clear ulcer formation, worsening of abdominal pain in existing colitis (ulcerative colitis), onset of colitis (ulcerative colitis) or ileitis (regional ileitis)
- inflammation of the oral mucosa (stomatitis) or gastric mucosa (gastritis), flatulence, bleeding from the large intestine and perforation of existing lesions in the large intestine
- rare (in 1 to 10 out of 10,000 users): intestinal ulcers followed by narrowing (stenosis) and obstruction.

#### Liver and biliary disorders

- yellow discoloration of the skin or eyes (jaundice)
- hepatitis accompanied by jaundice, in some cases with fatal outcome.

#### Renal and urinary disorders

- increased levels of urea in the blood
- presence of blood in the urine (hematuria)
- rare (in 1 to 10 out of 10,000 users): presence of excessive protein in the urine (proteinuria), syndrome accompanied by fluid retention in the body (nephrotic syndrome), inflammation of the kidneys accompanied by blood in the urine, fever, and flank pain (interstitial nephritis), impaired kidney function (renal dysfunction), including renal insufficiency.

#### General disorders and administration site conditions

- hypersensitivity reactions of the skin, including itching (pruritus), rash with severe itching and formation of welts (hives or urticaria), inflammation of the blood vessels (angiitis), painful bluish-red nodules in the skin (erythema nodosum), rash, skin inflammation with scaling (dermatitis exfoliativa), severe hypersensitivity reaction with (high) fever, red spots on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), rash with red (moist) irregular spots (erythema multiforme), severe, sudden (hypersensitivity) reaction accompanied by fever and blisters on the skin/peeling of the skin (toxic epidermal necrolysis), hair loss
- respiratory disorders, sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioneurotic edema), a rapid drop in blood pressure, resembling a shock-like condition, sudden shortness of breath (dyspnea), asthma attacks, fluid accumulation in the lungs (pulmonary edema)
- weight gain
- bleeding from the vagina
- high blood sugar levels (hyperglycemia), too much potassium in the blood, sometimes manifesting as muscle cramps, diarrhea, nausea, dizziness, headache (hyperkalemia)
- sugar in the urine (glycosuria)
- flushing, sweating (perspiration).

#### Side effects associated with the use of suppositories

- painful urge to defecate (tenesmus)
- inflammation of the rectum (proctitis)
- bleeding from the anus
- burning sensation, pain, irritation, itching.

#### 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](http://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?

Keep out of the sight and reach of children.

Store below 25 °C. Store in the original packaging.

Do not use this medicine after the expiry date. You can find it on the packaging after “Do not use after:” or “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 package and other information

What substances are in this medicine?

- The active substance in this medicine is indomethacin. Indomethacin suppository CF 50 mg and 100 mg, suppositories contain per suppository 50 mg and 100 mg indomethacin respectively.
- The other substance in this medicine is hard fat.

What does Indomethacin suppository CF look like and how much is in a package?

Suppositories in a strip. The strips are packed in a cardboard box. Each package contains 10, 20, 30, or 50 suppositories.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Centrafarm B.V.

Van de Reijtstraat 31-E 4814 NE Breda

Netherlands

Manufacturer

Centrafarm Services B.V. Van de Reijtstraat 31-E 4814 NE Breda Netherlands

Registered under

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This leaflet was last approved in October 2022.

More information about this medicine is available on the website of the CBG ([www.cbg-meb.nl](http://www.cbg-meb.nl)).