

PACKAGE LEAFLET: Information for the patient

COX-IN

Granules for oral suspension – 100 mg
(Nimesulide)

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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, please tell your doctor or pharmacist.

In this leaflet:

1. What Cox-in is and what it is used for
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1. WHAT COX-IN IS AND WHAT IT IS USED FOR

Cox-in contains the active substance nimesulide. It belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAIDs) and has analgesic properties.

Cox-in is used for the treatment of acute pain and menstrual pain.

Nimesulide should only be prescribed as second-line treatment.

Before prescribing Cox-in, your doctor will assess the benefits this medicine may give you against your risks of developing side effects.

2. BEFORE YOU TAKE COX-IN

Do not take Cox-in if you:

- are hypersensitive to nimesulide or to any of the other ingredients mentioned at the end of this leaflet (see section 6);
- have had a history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria) in response to acetylsalicylic acid or other non-steroidal antiinflammatory drugs;
- have had a history of hepatotoxic reactions to nimesulide;
- are taking / using concomitantly other potentially hepatotoxic drugs such as paracetamol or any other analgesic, or treatment with non-steroidal antiinflammatories;
- are an alcoholist or drug-addicted;
- have active gastric or duodenal ulcer, a history of recurrent ulceration or gastrointestinal bleeding, cerebrovascular bleeding or other active bleeding or bleeding disorders;
- have severe coagulation disorders;
- have severe heart failure;
- have severe renal impairment;
- have hepatic impairment;
- have fever and/or flu-like symptoms;
- are in the third trimester of pregnancy or breast-feeding.

Do not give Cox-in to a child aged less than 12.

Take special care with Cox-in

Ask your doctor before you take Cox-in.

The risk of undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration necessary to control the symptoms.

- If you do not see benefits, inform your doctor.
- If during nimesulide treatment you develop symptoms that suggest a liver condition, you should stop taking nimesulide and inform your doctor immediately. Symptoms suggesting a liver condition include loss of appetite, nausea, vomiting, abdominal pain, fatigue or dark urine.
- You should not use other analgesics during therapy with Cox-in.

- If during treatment with Cox-in you develop fever and / or flu-like symptoms (feeling generally unwell, chills or shivering), you should stop taking the product and inform your doctor.
- If you have ever suffered from peptic ulcers, gastrointestinal haemorrhage, ulcerative colitis or Crohn's disease, you should inform your doctor before taking Cox-in.
- If you suffer from renal or cardiac diseases, you should inform your doctor before taking Cox-in, since the use of Cox-in may result in deterioration of renal function.
- If you are elderly, your doctor may want to see you at regular intervals to make sure that Cox-in is not causing stomach, kidney, heart or liver problems.
- It should be used with caution in patients with bleeding tendency.
- If you are planning a pregnancy, you should inform your doctor since Cox-in may decrease fertility.
- Use of medicines such as Cox-in 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. If you have heart problems, previous stroke or think that you might be at risk for 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.
- If you develop severe allergic reactions, you should discontinue Cox-in at the first appearance of skin rash, lesions of soft tissues, or any sign of allergy, and contact your doctor.
- If you have an intolerance to some sugars, you should contact your doctor before taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is particularly important to inform your doctor that you are taking:

- analgesics, because concomitant use of NSAIDs with other NSAIDs or aspirin increases the risk of side-effects;
- corticosteroids (medicines to treat inflammatory conditions);
- anticoagulants (medicines to thin the blood);
- selective serotonin reuptake inhibitors (medicines to treat depression);

- cyclosporin (medicine used after transplantation or for the treatment of immune system disorders);
- methotrexate (medicine for the treatment of rheumatoid arthritis and cancer);
- diuretics or antihypertensives (medicines to control heart conditions or blood pressure);
- lithium (medicine to treat depression or similar conditions).

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor or pharmacist before taking this medicine.

Cox-in must not be used during the last trimester of pregnancy; it can cause problems for the baby and during labour.

If you are planning a pregnancy, you should inform your doctor since Cox-in may decrease fertility.

If you are in the first or second trimester of pregnancy, do not exceed the dose and duration of treatment prescribed by your doctor.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding.

Cox-in must not be used during breastfeeding.

Driving and using machines

Do not drive or use machines if Cox-in makes you feel dizzy or sleepy.

Important information about some of the ingredients of Cox-in

Cox-in contains sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE COX-IN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The usual dose is one sachet 100 mg twice a day after meals.

Use Cox-in for the shortest possible period of time and for not more than 15 days in any single course of treatment.

If you take more Cox-in than you should

If you take more Cox-in than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

In case of overdose, you may develop one of the following symptoms: nausea, vomiting, headache, drowsiness, dizziness, gastric ulcer, breathing difficulty etc.

If you forget to take Cox-in

If you forget to take one dose, take the next dose in its usual time. Do not take a double dose to make up a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cox-in can cause side effects, although not everybody gets them.

If any of the following happens, stop taking the medicine and tell your doctor immediately, since these may indicate rare severe side effects that require medical attention:

- stomach discomfort or pain, loss of appetite, nausea, vomiting, gastrointestinal bleeding or black stool;
- skin disorders such as rash or redness;
- wheezing or shortness of breath;
- yellowing of your skin or the whites of your eyes (jaundice);
- unexpected change in the amount or colour of urine;
- swelling of your face, feet or legs;
- fatigue.

General side effects of non-steroidal anti-inflammatory drugs (NSAIDs):

The use of some NSAIDs may be associated with an increased risk of thrombotic events (e.g. myocardial infarction and stroke).

Oedema, hypertension, and cardiac failure have been reported in association with NSAID treatment.

The most commonly-observed adverse events are of gastrointestinal nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur.

Side effects that may occur with nimesulide:

Blood and lymphatic system disorders: anaemia, decrease in white cells in the blood, increase in certain white cells (eosinophils) in the blood, decrease in platelets in the blood causing bleeding under the skin or in other parts of the body.

Immune system disorders: hypersensitivity.

Metabolism and nutrition disorders: hyperkalemia.

Psychiatric disorders: anxiety, nervousness, nightmares.

Nervous system disorders: dizziness, headache, sleepiness, encephalopathy.

Eye disorders: visual disturbances, blurring of vision.

Ear and labyrinth disorders: vertigo.

Cardiac disorders: tachycardia.

Vascular disorders: hypertension, blood pressure fluctuation, skin flushing.

Respiratory, thoracic and mediastinal disorders: shortness of breath, asthma.

Gastrointestinal disorders: diarrhoea, nausea, vomiting, melaena, gastrointestinal bleeding, duodenal ulcer and perforation, gastric ulcer and perforation, stomach pain, indigestion, sore mouth, constipation, flatulence.

Hepatobiliary disorders: hepatitis, sometimes very severe causing jaundice and stoppage of bile flow.

Skin and subcutaneous tissue disorders: itching, rash, sweating, redness of the skin, dermatitis, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis, urticaria, face oedema.

Renal and urinary disorders: discomfort in urination or stoppage of urination, haematuria, renal failure, nephritis.

General disorders: oedema, malaise, tiredness, hypothermia.

Investigations: increased hepatic enzymes.

Talk to your doctor or pharmacist, if you get any of these side effects or any side effects not listed in this leaflet.

5. HOW TO STORE COX-IN

Keep out of the reach and sight of children!

Do not use Cox-in after the expiry date which is stated on the package.

Store below 25°C!

Keep in the original package to protect it from light and humidity.

6. FURTHER INFORMATION

What Cox-in contains

The active substance is nimesulide.

Each sachet with granules contains 100 mg nimesulide.

The other ingredients are: sucrose, lactose, orange flavor, citric acid, sodium lauryl sulphate.

Contents of the pack

Box with 30 sachets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in January 2024.