

PACKAGE LEAFLET: INFORMATION FOR THE USER

piroxicam cinfa 20 mg dispersible tablets piroxicam

Read all of this 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.
- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What piroxicam cinfa is and what it is used for
2. What you need to know before you take piroxicam cinfa
3. How to take piroxicam cinfa
4. Possible side effects
5. How to store piroxicam cinfa
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1. What piroxicam cinfa is and what it is used for

piroxicam cinfa is an anti-inflammatory medicine that belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

piroxicam cinfa is used to relieve some symptoms caused by osteoarthritis (degenerative joint disease), rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine), such as swelling, stiffness and joint pain. It does not cure arthritis, but it helps relieve some symptoms only as long as you continue to take it.

Before prescribing piroxicam, your doctor must assess the benefits of this medicine in relation to the risk of developing adverse reactions. Due to treatment with piroxicam, you may need to have regular checks; your doctor will tell you how often these will be.

Your doctor will only prescribe piroxicam to you when other non-steroidal anti-inflammatory drugs (NSAIDs) have not relieved your symptoms.

2. What you need to know before you take piroxicam cinfa

Do not take piroxicam cinfa

- If you are allergic (hypersensitive) to piroxicam or any of the other ingredients of this medicine.
- If you have or have previously had a stomach or intestinal ulcer, bleeding or perforation.
- If you have or have previously had gastrointestinal disorders (inflammation of the stomach or intestines) that predispose to bleeding disorders such as ulcerative colitis (inflammation of the colon

and rectum), Crohn's disease (inflammation of the intestines), stomach or bowel cancers, or diverticulitis (inflammation or infection of the pouches/pockets in the colon).

- If you are taking other non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 selective NSAIDs and acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever.
- If you are taking anticoagulants such as warfarin to prevent blood clots.
- If you have previously had a severe allergic reaction to other NSAIDs or any other medicines, especially serious skin reactions (regardless of severity) such as exfoliative dermatitis (intense reddening of the skin, with skin peeling off in scales or layers), blistering reactions (Stevens-Johnson syndrome, with red blisters, erosion and crusty or bleeding skin) or toxic epidermal necrolysis (a disease with blistering and peeling of the top layer of skin). Or if you have other allergy symptoms such as asthma attacks, severe nasal congestion or another allergic reaction such as itchy skin, rash, swelling of the face, lips or tongue that make it difficult to breathe, or wheezing.
- If you have acute liver or kidney disease.
- If you have severe heart failure (your heart has difficulty pumping blood).
- If you have blood clotting disorders.
- If you are in the last three months of pregnancy.

If any of these apply to you, do not take piroxicam. Tell your doctor immediately.

Warnings and precautions

Skin rashes that may prove life-threatening for the patient (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported when using piroxicam cinfa. These rashes initially appear as red spots or circular blotches, often with a blister in their centre.

Other signs that may appear include sores in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

Those skin rashes that may threaten the patient's life are often accompanied by flu-like symptoms. The rash may progress to form widespread blisters or flaking of the skin.

The highest risk of the appearance of serious skin reactions is during the first few weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis when taking piroxicam cinfa, you should not take piroxicam cinfa again at any time.

If you develop a rash or any of these skin symptoms you should stop taking piroxicam cinfa, visit your doctor immediately and tell him/her that you are taking this medicine.

Take special care with piroxicam cinfa and always tell your doctor before using this medicine, as with other non-steroidal anti-inflammatory drugs.

piroxicam cinfa can cause severe reactions in the stomach and intestines, such as pain, bleeding, ulcers and perforation.

You should stop treatment with piroxicam and talk to your doctor if you have stomach pain or any sign of bleeding in the stomach or intestines, such as black or bloody stools or vomiting blood.

You should stop treatment with piroxicam immediately and talk to your doctor if you have any allergic reactions such as skin rash, swelling of the face, wheezing or difficulty breathing.

If you are over the age of 70, your doctor may reduce the duration of the treatment and carry out checks more often while you are taking piroxicam.

If you are over the age of 70 or you are taking other medications such as corticosteroids or certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or acetylsalicylic acid to prevent blood clots, your doctor may prescribe a medicine to protect your stomach or intestines together with piroxicam cinfa.

Do not take this medicine if you are over the age of 80.

If you have or have previously had any medical problem or any type of allergy or if you are not sure whether you can take piroxicam, talk to your doctor before taking this medicine.

Make sure your doctor knows about all the medicines you are taking, including those obtained without a prescription.

Medicines like piroxicam cinfa may be associated with a moderate increase in the risk of suffering heart attacks (“myocardial infarctions”) or strokes. This risk is more likely to occur when high doses and long-term treatments are used. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke or think you might be at risk of suffering these conditions (for instance, you have high blood pressure, diabetes, increased cholesterol or are a smoker), ask your doctor or pharmacist about this treatment.

Furthermore, this type of medicine can cause fluid retention, particularly in patients with heart failure and/or high blood pressure (hypertension).

You should also take piroxicam cinfa with caution and always following your doctor’s instructions in the following situations:

- If you have moderate or mild kidney or liver disease.
- If you have an infection, as it could mask fever and mistakenly make you believe that you are better or that the infection is not serious.
- You should see an ophthalmologist if you have eye problems during treatment with piroxicam.
- If you have asthma.

Other medicines and piroxicam cinfa

Tell your doctor or pharmacist if you are using, have used or might use any other medicines, including medicines obtained without a prescription.

Certain medicines can interact with each other. Your doctor may limit your use of piroxicam or other medicines, or you may need to change to a different medicine. It is especially important to tell your doctor if you are taking any of the following medicines:

- Aspirin or other non-steroidal anti-inflammatory drugs to relieve pain.
- Corticosteroids, which are medicines used to treat many diseases such as allergies, hormonal disorders and inflammatory diseases.
- Anticoagulants such as warfarin to prevent blood clots.
- Medicines for depression called selective serotonin reuptake inhibitors (SSRIs).
- Medicines to prevent platelet aggregation such as acetylsalicylic acid.
- Lithium (medicine used for bipolar depression).
- Methotrexate (medicine used in rheumatoid arthritis and to treat certain cancers).
- Ticlopidine (antiplatelet medicine).
- Quinolones (anti-infection medicines).
- Certain diuretics (medicines used to treat fluid retention in high blood pressure).
- Sulfonyleureas (oral antidiabetic medicines).
- Cyclosporine or tacrolimus (medicines used in transplant patients).
- Antihypertensives (medicines used to treat high blood pressure).

- Digoxin (medicine used to treat heart problems): concomitant treatment with digoxin and piroxicam does not affect plasma levels of either of these drugs.

Talk to your doctor immediately in any of these situations.

piroxicam cinfa with food and drink

piroxicam cinfa can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

Since the administration of medicines like piroxicam cinfa has been associated with an increased risk of congenital anomalies (malformations) and miscarriages, its administration is not recommended during the first and second trimesters of pregnancy, unless it is considered absolutely necessary. In these cases, the dose and duration will be limited to the minimum, whenever possible.

The administration of piroxicam cinfa is contraindicated in the third trimester.

For women of child-bearing age, it must be taken into account that medicines like piroxicam cinfa have been associated with reduced fertility.

The use of piroxicam cinfa is not recommended during breast-feeding, as its clinical safety has not been established.

Driving and using machines

If you notice any dizziness, vertigo, visual disturbances or drowsiness while taking piroxicam cinfa, do not drive or operate dangerous machinery until these symptoms subside or you know how you tolerate the medicine.

3. How to take piroxicam cinfa

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

piroxicam cinfa dispersible tablets can be swallowed whole with a little liquid or can be dissolved in a glass of water.

Your doctor will give you regular check-ups to make sure you are taking the right dose of piroxicam. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms. Under no circumstances should you change your dose without speaking to your doctor first.

Your doctor may prescribe piroxicam with another medicine to protect your stomach and intestines from potential adverse reactions.

Do not increase the dose.

If you feel that the medicine is not very effective, talk to your doctor.

Adults and elderly patients:

The maximum daily dose is 20 mg of piroxicam taken as a single daily dose.

If you are over the age of 70, your doctor may prescribe a lower daily dose and reduce the duration of treatment.

Use in children:

Its use in children is not recommended.

If you have any questions about the use of this medicine, ask your doctor.

If you take more piroxicam cinfa than you should

In case of overdose or accidental ingestion, go immediately to the nearest medical centre. Take this leaflet with you.

If you forget to take piroxicam cinfa

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose, take it as soon as you remember. If it is almost time to take the next dose, do not take the one you missed and wait to take the next 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, piroxicam cinfa can cause side effects, although not everybody gets them.

The side effects of piroxicam cinfa vary in intensity from one person to another but are generally mild and transient.

A list of side effects is given below. They have been classified using the following definitions of frequencies: Very common (at least 1 in 10 patients), common (at least 1 in 100 patients), uncommon (at least 1 in 1,000 patients), rare (at least 1 in 10,000 patients), and very rare (less than 1 in 10,000 patients). When not possible to assign a category, it is described as “unknown frequency”.

Blood and lymphatic system disorders:

Rare: decreases in haemoglobin and the haematocrit (indicators of anaemia), reduction in the blood platelet and white cell count, as well as different types of anaemia and nose bleeds.

Immune system disorders: Cases of allergic reactions (hypersensitivity) have been reported, e.g. anaphylaxis and “serum sickness”. Unknown frequency.

Metabolism and nutrition disorders:

Common: anorexia (lack of appetite).

Rare: decrease or increase in blood sugar levels.

Unknown frequency: Weight gain or loss.

Psychiatric disorders: Rarely symptoms of depression, nervousness, hallucinations, mood changes, nightmares and mental confusion may occur. More commonly insomnia (difficulty sleeping) can occur.

Nervous system disorders:

Common: headache.

Uncommon: dizziness, drowsiness.

Rare: depression, nervousness, hallucinations, mood changes, nightmares, confusion, aseptic meningitis (meningitis not caused by bacteria), vertigo and tingling sensation.

Eye disorders:

Rare: swelling of the eyelids, blurred vision and irritation in the eyes.

Ear and labyrinth disorders:

Rare: altered sense of hearing and ringing in the ears.

Cardiac and vascular disorders:

Common: fluid retention (oedema), mainly of the ankles (swollen ankles), and hypertension (increased blood pressure).

Rare: medicines like piroxicam cinfa may be associated with a moderate increase in the risk of heart attacks (“myocardial infarctions”) or stroke.

Unknown frequency: palpitations (noticeable heart beats).

Respiratory, thoracic and mediastinal disorders:

Rare: Difficulty breathing (dyspnoea), bronchospasm (temporary reduction in the diameter of the bronchi) and epistaxis (nose bleeds).

Gastrointestinal disorders:

Common: constipation, gases, diarrhoea, abdominal pain, indigestion (dyspepsia), loss of appetite, inflammation of the oral mucosa, upset stomach, inflammation of the stomach mucosa (gastritis), nausea and vomiting, which in most cases does not make it necessary to stop the treatment.

Uncommon: digestive bleeding including vomiting blood (haematemesis) and bloody stools (melena).

Unknown frequency: inflammation of the pancreas (pancreatitis).

Prolonged administration of doses of 30 mg or more involve a greater risk of gastrointestinal side effects.

Hepatobiliary disorders:

Uncommon: occasional elevation of hepatic transaminases (indicators of liver function).

Rare: liver inflammation (hepatitis) and jaundice (yellowing of the skin due to increased bilirubin in the blood).

Skin and subcutaneous tissue disorders:

Uncommon: rash, redness and itching of the skin.

Rare: separation of the nail (onycholysis), hair loss, sensitivity to the sun, blistering of the skin.

Very rare: Skin rashes that may be life-threatening to the patient (Stevens-Johnson syndrome, toxic epidermal necrolysis) may also occur (see section 2).

Renal and urinary disorders:

Rare: reversible increase of nitrogen and creatinine in the blood (indicators of kidney function).

General disorders:

Rare: malaise.

Others:

Rare: serious allergic reactions, angioneurotic oedema (swelling of the tongue, lips and throat), vasculitis (inflammation of the blood vessels), “serum sickness” (rash accompanied by fever, inflamed lymph nodes and joint pain), certain disorders of the immune system.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Y

5. How to store piroxicam cinfa

Please store below 25° C.

Keep this medicine out of the sight and reach of children.

Do not use piroxicam cinfa after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What piroxicam cinfa contains

- The active substance is piroxicam. Each tablet contains 20 mg of piroxicam.
- The other ingredients are: microcrystalline cellulose (E-460), calcium hydrogen phosphate dihydrate, maize starch, sodium carboxymethyl starch, sodium stearyl fumarate, magnesium stearate (E-470b) and talc (E-553b).

What piroxicam cinfa looks like and contents of the pack

piroxicam cinfa is supplied in the form of yellowish-white tablets scored dispersible tablets. Each package contains 20 tablets.

Marketing authorisation holder and manufacturer

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