

## **Package leaflet: Information for the user**

### **piroxicam cinfa 20 mg dispersible tablets**

**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, pharmacist or nurse.
- 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, pharmacist or nurse. 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
6. Contents of the pack and other information

#### **1. What piroxicam cinfa is and what it is used for**

Piroxicam cinfa is an antiinflammatory medicine that belongs to the group of medicines called nonsteroidal antiinflammatory 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 pain of the joints. It does not cure osteoarthritis, 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 nonsteroidal antiinflammatory 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 to piroxicam or any of the other ingredients of this medicine (listed in section 6).
- If you have had a stomach or intestinal ulcer, bleeding or perforation.
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- If you have or have previously had gastrointestinal disorders (inflammation of the stomach or intestine) that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, stomach or bowel cancer, or diverticulitis (inflammation or infection of the pouches/pockets in the colon).
- If you are taking other nonsteroidal antiinflammatory drugs (NSAIDs), including selective COX-2 inhibitors and acetylsalicylic acid (aspirin), present in many medicines used to relieve pain and lower fever.

- If you are taking anticoagulants such as warfarin, coumarins or the new oral anticoagulants including apixaban, dabigatran and rivaroxaban, used to prevent blood clots.
- If you have previously suffered a severe allergic reaction to piroxicam, other NSAIDs or 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, characterised by red blisters, erosion and crusty or bleeding skin) or toxic epidermal necrolysis (a disease with blistering and peeling of the superficial layers of the skin), or if you have experienced other allergic manifestations such as asthma attacks, severe nasal congestion or other allergic reactions such as itching of the skin, rash, swelling of the face, lips or tongue, causing breathing difficulties or wheezing in the chest.
- If you develop a rash or skin symptoms, stop taking piroxicam immediately, seek urgent medical advice and inform your doctor that you are taking this medicine..
- If you have acute liver or kidney disease.
- If you have severe heart failure.
- 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**

Talk to your doctor or pharmacist before taking piroxicam cinfa.

#### Gastrointestinal risks

In the same way as the rest of the nonsteroidal antiinflammatory drugs, piroxicam cinfa can cause severe reactions in the stomach and intestine, such as pain, bleeding, ulcers and perforation. The administration of doses of over 20 mg a day implies an increased risk of gastrointestinal side effects. Adverse effects can be minimised by using the lowest effective dose for the shortest possible time.

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.

In the event of any new abdominal sign or symptom, or any gastrointestinal complication during treatment, suspend the medication and consult your doctor immediately.

#### Skin risks

There have been reports of skin rashes that may prove life-threatening (Stevens-Johnson syndrome and toxic epidermal necrolysis) when using piroxicam. These rashes initially appear as red spots or circular blotches, often with a blister at the centre.

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

Potentially life-threatening skin rashes 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 using piroxicam, you should not use the medication again at any time.

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

## Cardiovascular and cerebrovascular risks

Medicines like piroxicam cinfa may be associated with a moderate increase in the risk of suffering heart attack (“myocardial infarction”) or stroke. 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).

## Other risks

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 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 intestine 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 using this medicine.

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

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 severe dehydration.
- 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 suffer from asthma.
- If you are taking anticoagulants.

## **Other medicines and piroxicam cinfa**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Certain medicines can interact with each other. Your doctor may limit your use of piroxicam and/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 nonsteroidal antiinflammatory 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, coumarins or the new oral anticoagulants (apixaban, dabigatran and rivaroxaban) 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).
- Sulfonylureas (oral antidiabetic medicines).
- Cyclosporine or tacrolimus (medicines used in transplant patients).
- Antihypertensive agents (medicines used to treat high blood pressure).
- Thrombolytic agents (medicines used to treat stroke or heart attack).
- Digoxin: concomitant treatment with digoxin and piroxicam does not affect the plasma levels of either of these drugs.

Talk to your doctor immediately in any of these situations.

### **Piroxicam cinfa with food, drink and alcohol**

Taking piroxicam cinfa with food may cause a small delay in effect; administration between meals is therefore advised.

Alcoholic beverages should not be consumed during treatment with this medicine, as it may increase the risk of side effects.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Since the administration of medicines like piroxicam cinfa has been associated with an increased risk of suffering congenital anomalies/miscarriages, its administration is not recommended during the first and second trimester of pregnancy, unless it is considered to be absolutely necessary. In these cases, the dose and duration will be kept to the minimum.

The use of piroxicam is contraindicated during the third trimester of pregnancy.

Women of child-bearing age must take into account that medicines like piroxicam cinfa have been associated with reduced fertility.

Tell your doctor if you are breast-feeding or about to start breast-feeding. The use of piroxicam cinfa is not recommended during breast-feeding, since its clinical safety has not been established in this situation.

### **Driving and using machines**

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

**Piroxicam contains sodium.** This medicine contains less than 23 mg (1 mmol) of sodium per tablet; it is essentially “sodium-free”.

## **3. How to take piroxicam cinfa**

Always take this medicine exactly as your doctor or pharmacist 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 take more piroxicam than you should**

Immediately contact your doctor or pharmacist or emergency department of your hospital.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

#### **If you forget to take piroxicam**

Take it as soon as you remember it. If it is almost time to take the next dose, do not take the one you missed and wait to take the next dose. Do not take a double dose to make up for 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, this medicine can cause side effects, although not everybody gets them. Piroxicam is generally well tolerated.

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

A list of side effects is given below. It is important that you tell your doctor if you notice any discomfort.

**Common:** may affect up to 1 in 10 people

- Reduced red blood cells, white blood cells and platelets in blood; elevation of certain white blood cells (eosinophilia)
- Loss of appetite, increased blood sugar levels
- Dizziness, headache, drowsiness, vertigo
- Buzzing sounds in the ears
- Abdominal pain or discomfort, constipation, diarrhoea, upper abdominal discomfort, flatulence, nausea, vomiting, indigestion
- Itching of the skin, rash

- Ankle swelling (oedema)
- Reversible blood urea nitrogen (BUN) elevation or increased liver enzymes (transaminases) that can affect some medical tests, weight gain

**Uncommon:** may affect up to 1 in 100 people

- Palpitations
- Inflamed gums
- Reversible creatinine elevation that can affect some medical tests
- Stevens-Johnson syndrome, toxic epidermal necrolysis, shedding of nails, skin reactions due to allergy to light, skin rash with formation of vesicles or blisters
- Low blood sugar levels.
- Blurred vision

**Very rare:** may affect up to 1 in 10,000 people

- Stevens-Johnson syndrome, toxic epidermal necrolysis, shedding of nails, skin reactions due to allergy to light, skin rash with formation of vesicles or blisters

**Not known:** frequency cannot be estimated from the available data

- Reduced red blood cell counts due to failed red cell formation or premature destruction
- Serious allergic reaction affecting the entire body (anaphylaxis), rash accompanied by fever, swelling of the lymph nodes and joint pain (serum sickness)
- Fluid retention
- Depression, sleep disturbances, hallucinations, insomnia, confusion, mood changes, restlessness
- Inflammation of the membranes covering the brain and spinal cord caused by viruses, numbness or tingling sensation of the extremities
- Irritation or inflammation of the eyes
- Hearing problems
- Blood vessel inflammation, high blood pressure
- Bronchial spasms obstructing air passage into the lungs, breathing difficulty, nosebleed
- Reaction to suppositories with pain, burning sensation, itching in the anorectal zone or urgent need to defecate, accompanied by colic pain and in rare cases by rectal bleeding, inflammation of the gastric mucosa, gastrointestinal bleeding including vomiting with blood or dark stools due to bleeding, pancreatic inflammation, intestinal wall wounds or perforations
- Fatal inflammation of the liver, yellowing of the skin and mucous membranes
- Hair loss, serious skin reactions that may prove fatal (exfoliative dermatitis, erythema multiforme, non-thrombocytopenic purpura)
- Kidney problems such as nephrotic syndrome and interstitial glomerulonephritis (often manifesting with kidney inflammation and protein loss in urine), and renal failure
- Decreased female fertility
- Laboratory test alterations, weight loss
- Fixed drug eruption (may appear as round or oval plaques with redness and swelling of the skin, blisters (urticarial), itching)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store piroxicam cinfa**

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

Do not use this medicine 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 store at temperatures above 25°C

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 (type A)(potato), 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 as oblong, biconvex, white-yellow dispersible tablets scored on one side and marked with “P20C” on the other. The medicinal product is supplied in PVC-PVDC/Aluminium blisters. Each pack contains 20 tablets.

### **Marketing Authorisation Holder and Manufacturer**

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