



Package leaflet: Information for the patient

Piroxicalm 10 mg capsules

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.

What is in this leaflet

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

Piroxicalm is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This means it will help to relieve pain and reduce swelling affecting joints and muscles. Piroxicalm is used to relieve some symptoms caused by osteoarthritis (joint disease), rheumatoid arthritis, and ankylosing spondylitis (rheumatism of the spine) such as swelling, stiffness and joint pain. This medicine does not cure arthritis and will help you only as long as you continue to take it. Your doctor will only prescribe Piroxicalm to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take Piroxicalm

Do not take Piroxicalm:

- If you have previously had or currently have a stomach or intestinal ulcer, bleeding or perforation
- If you have, or have previously had disorders of the stomach or intestines such as ulcerative colitis, Crohn's disease, gastrointestinal cancers or diverticulitis (inflamed or infected pouches/pockets in the colon)
- If you are taking other NSAIDs such as ibuprofen, celecoxib or acetylsalicylic acid (aspirin), 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 previously had an allergic reaction to piroxicam, (the active ingredient in this medicine) or any of the other ingredients of this medicine, other NSAIDs or any other medications, especially serious skin reactions (regardless of severity) such as erythema multiform (patches of red, raised skin), Stevens-Johnson syndrome or toxic epidermal necrolysis.
- If you have heart failure.

If the above applies to you, do not take this medicine and talk to your doctor or pharmacist.

Warnings and precautions

Take special care with Piroxicalm:

- Before prescribing Piroxicalm (piroxicam), your doctor will assess the benefits this medicine may give you against your risk of developing side effects. Your doctor may need to give you check-ups and will tell you how often you need to be checked during treatment with Piroxicalm.
- Medicines such as Piroxicalm 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 or if you are a smoker.
- Take special care with Piroxicalm as like all NSAIDs, Piroxicalm can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration and perforation.
- You should stop taking Piroxicalm immediately and tell your doctor if you have severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements or vomiting blood.
- Your doctor may prescribe Piroxicalm together with another medicine to protect your stomach and intestines from side effects, particularly if you are over 70 years old, or you are taking other medicines like corticosteroids (medicines given to treat a variety of conditions such as allergies and hormone imbalances), certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or low dose acetylsalicylic acid to help prevent heart attacks or stroke.
- If you experience problems with your eyesight while taking Piroxicalm tell your doctor as you may need to have your eyes checked.

Talk to your doctor or pharmacist before you take Piroxicalm if you suffer from or have suffered in the past from any of the following conditions:
- liver disease
- kidney disease
- high blood pressure, heart problems or stroke
- high cholesterol or hardening of the arteries
- diabetes
- bleeding in the brain or any other blood clotting disorder.

Patients over 70 years of age

If you are over 70 years old, your doctor may wish to minimise the length of your treatment and to see you more often while you are taking Piroxicalm. You should not take this medicine if you are over 80 years of age.

Other medicines and Piroxicalm

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Medicines can sometimes interfere with each other. Your doctor may limit your use of Piroxicalm or other medicines, or you may need to take a different medicine.

Do not take piroxicalm together with:

- acetylsalicylic acid or other non-steroidal anti-inflammatory medicines for pain relief
- anticoagulants such as warfarin to prevent blood clots

Tell your doctor before you take piroxicalm if you are taking any of the following medicines:

- corticosteroids, which are medicines given to treat a variety of conditions such as allergies and hormone imbalances
- low dose acetylsalicylic acid (75 mg) to help prevent heart attack or stroke
- digoxin or digitoxin, which are used to treat heart conditions
- certain medicines for depression such as lithium or selective serotonin re-uptake inhibitors (SSRIs)
- antihypertensives to treat high blood pressure
- methotrexate, which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis
- ciclosporin, which is given to help prevent rejection of transplanted organs
- aminoglycoside antibiotics, such as streptomycin, which are used to treat serious infections
- probenecid, a medicine used to treat gout
- diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems
- medicines for diabetes that are taken by mouth, such as chlorpropamide.

Piroxicalm with food and drink

Piroxicalm should be taken with food.

Pregnancy and breast-feeding

Piroxicalm should be avoided in pregnancy and breast-feeding. Piroxicalm may make it more difficult to become pregnant. Tell your doctor if you are trying for a baby or having tests for infertility, as piroxicam may not be suitable for you. 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.

Driving and using machines

This medicine can cause some people to feel dizzy, drowsy, tired or have problems with their vision. If you are affected, do not drive or operate machinery.

Important information about some of the ingredients of Piroxicalm

Piroxicalm contains lactose, a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking Piroxicalm.

3. How to take Piroxicalm

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

- Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Piroxicalm.
- Your doctor will adjust your treatment to the lowest dose that best controls your symptoms. Under no circumstances should you change your dose without first speaking to your doctor.
- Swallow your capsules whole with a glass of water. It is best to take your capsules at the same time each day with food or soon after eating.

Adults

The maximum daily dose of Piroxicalm is 20 milligrams taken as one single daily dose.

Elderly

If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment. If you feel that the medicine is not very effective, always talk to your doctor. Do not increase the dose.

If you take more Piroxicalm than you should

If you accidentally take too much Piroxicalm contact your doctor at once or go to the nearest hospital.

If you forget to take Piroxicalm

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a missed dose.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately and stop taking piroxicalm if you experience any of the following symptoms:

- any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements or vomiting blood
- sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe skin reactions including a rash with blisters (vesiculo-bullous reactions) and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or extensive peeling of the skin (toxic epidermal necrolysis)
- yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems

The most common side effects are:

- diarrhoea, constipation, wind
- feeling sick (nausea), vomiting, anorexia
- sore mouth and/or lips
- stomach ache, indigestion, abdominal pain/discomfort
- stomach (peptic) ulcers, inflammation of the stomach lining (gastritis) or worsening of the symptoms associated with colitis or Crohn's disease.

Other side effects of Piroxicalm include:

Effects on your heart and circulation: Piroxicalm may be associated with fast or pounding heartbeat, high blood pressure, fluid retention causing swelling of the feet, hands or other parts of the body (oedema) and a small increased risk of heart attack (myocardial infarction) or stroke.

Effects on your nervous system: dizziness, vertigo (a spinning sensation), headache, changes in sleep patterns, depression, nervousness, hallucinations, mood alterations, mental confusion, pins and needles.

Effects on your skin: rashes, blistering, peeling, itching, redness, tenderness, thickening or scaling of skin, loosening or splitting of fingernails, hair loss and increased sensitivity of the skin to sunlight. Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely (see section 2). Vesiculo-bullous reactions (a rash with blisters) may occur.

Effects on blood and medical tests: abnormalities in the blood e.g. decreased haemoglobin and changes in the red and white blood cells which may result in unusual bruising or bleeding or increased risk of infection. Changes in other biochemical tests including those for kidney (e.g. increased creatinine) and liver (e.g. increased serum transaminase) function. Changes in blood sugar levels may also occur.

Effects on your eyes and ears: hearing impairment, ringing in ears, swollen eyes, blurred vision, eye irritation.

Other effects: fever, nosebleeds, weight increase or decrease, inflamed pancreas (which may lead to severe pain in the upper abdomen or back), feeling unwell, general aches and pains, unusual weakness or tiredness without any other symptoms.

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

5. How to store Piroxicalm

- 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 carton and blister. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not use any Piroxicalm pack that is damaged.
- Do not throw away any medicines via wastewater . 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 Piroxicalm contains

The active substance in Piroxicalm is piroxicam
Piroxicalm 10 mg: each capsule contains 10 mg piroxicam

The other ingredients are: lactose monohydrate, magnesium stearate, croscarmellose sodium.
The capsule shell contains: gelatine, titanium dioxide (E171), erythrosine (E127), indigo carmine (E132).

What Piroxicalm looks like and contents of the pack

Piroxicalm capsules are red and white, size 3 hard capsules. Piroxicalm 10 mg is available in boxes of 30 capsules.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal - Lebanon.
P.O. Box 90201 Jdeidet-el-Metn; Beirut - Lebanon
E-mail: pharmaline@maliagroup.com
Web: www.pharmaline.com.lb

Registration N° for Piroxicalm 10 mg capsules in Lebanon: 27514/93

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers Union of Arab Pharmacists

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