

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

PIXICAM 20 CAPSULES

Piroxicam 20mg

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 health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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1. WHAT PIXICAM CAPSULES IS AND WHAT IT IS USED FOR

Piroxicam belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). This means it will help to relieve pain and reduce swelling in the joints. Pixicam 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 if you continue to take it. Your doctor will only prescribe Pixicam to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. BEFORE YOU TAKE PIXICAM CAPSULES

Do not take PIXICAM CAPSULES if you

- are allergic (hypersensitive) to piroxicam or any of the other ingredients of Pixicam Capsules.
- are allergic to other NSAIDs or any other medications, especially in form of serious skin reactions (regardless of severity) such as exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), Stevens-Johnson syndrome (symptoms are a rash, blistering or peeling of the skin, mouth, eyes or genitals) or toxic epidermal necrolysis (a disease with blistering and peeling of the top layer of skin).
- 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.
- have previously had or currently have a stomach or intestinal ulcer, bleeding, or perforation.
- 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).
- are taking anticoagulants, such as warfarin, to prevent blood clots.
- suffer from severe heart failure.
- are in the last three months of pregnancy.

If any of the above applies to you, tell your doctor immediately and do not take Piroxicam capsules.

Potentially life-threatening skin rashes (Steven-Johnsons syndrome, toxic epidermal necrolysis) have been reported with the use of piroxicam, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for includes ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Piroxicam, you must not be re-started on Piroxicam at any time. If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine.

Take special care with Pixicam Capsules

Before treatment with Pixicam capsules, your health care provider 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 Pixicam capsules. Medicines

such as Piroxicam capsules 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. Do not exceed the recommended dose or duration of treatment.

Warnings and precautions

Tell your doctor before you take Piroxicam capsules 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
- asthma
- diabetes.
- If you have or had any other medical problems or any allergies or if you are not sure as to whether you can use Piroxicam capsules tell your doctor before taking this medicine.
- You should stop taking Piroxicam capsules immediately and tell your doctor if you have any allergic reaction such as a skin rash, swelling of the face, wheezing or difficulty breathing.
- Take special care with Piroxicam capsules as like all NSAIDs, Piroxicam capsules can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration, and perforation.
- You should stop taking Piroxicam capsules immediately and tell your doctor if you have 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 Piroxicam capsules 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 (aspirin) to help prevent heart attacks or stroke.

Piroxicam capsules may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

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 Piroxicam capsules. You should not take this medicine if you are over 80 years of age

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Medicines can sometimes interfere with each other. Your doctor may limit your use of Piroxicam capsules or other medicines, or you may need to take a different medicine.

The following medicines must not be taken with Piroxicam capsules:

- Aspirin or other non-steroidal anti-inflammatory drugs for pain relief.
- Anticoagulants such as warfarin to prevent blood clots.

Tell your doctor before you take Piroxicam capsules 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 aspirin (75 mg) to help prevent heart attack or stroke
- Certain medicines used to treat heart conditions known as cardiac glycosides, such as digoxin
- 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 or tacrolimus, which are given to help prevent rejection of transplanted organs
- Quinolone antibiotics e.g.ciprofloxacin, which are used to treat various infections
- Mifepristone, a medicine used to terminate pregnancy
- Diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems.

Taking Piroxicam Capsules with food and drink

Piroxicam capsules should be taken with or after food.

Pregnancy and breast-feeding

If you are pregnant, planning pregnancy or breast-feeding tell your doctor before you take Piroxicam capsules. Do not take Piroxicam capsules if you are in the last three months of pregnancy. It is not usually recommended at other stages of pregnancy, but you may be able to take it if your doctor advises that it is necessary for you.

If you are trying to become pregnant or being investigated for infertility, withdrawal of Piroxicam capsules should be considered. Piroxicam capsules may increase the risk of miscarriage in early pregnancy.

Ask your health care provider for advice before taking any medicine.

Driving and using machines

These capsules 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

3. HOW TO TAKE PIXICAM CAPSULES

Always take Pixicam capsules exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Piroxicam capsules. 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.

The usual dose is:

Adults:

- The maximum daily dose of Piroxicam capsules is 20mg 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 Pixicam Capsules than you should

If you accidentally take too much Piroxicam capsules, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Piroxicam capsules left or not.

If you forget to take Pixicam Capsules

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 forgotten dose.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pixicam capsules can cause side effects, although not everybody gets them.

Stop taking Piroxicam capsules and contact your doctor immediately if you notice signs of:

- an allergic reaction: asthma or worsening of asthma, narrowing of the airways causing difficulty breathing/wheezing, rash, irregular raised patches with severe itching (hives), swelling of the face, lips, throat or tongue, blood vessel inflammation, serum sickness (rash, fever, joint pain, enlarged lymph nodes).
- allergic reaction involving purple spots on the skin, joint pain, abdominal pain, and kidney dysfunction (Henoch-Schoenlein purpura)
- skin reactions such as severe rash involving reddening, peeling, and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), severe form of skin rash with flushing, fever, blisters, or ulcers (Stevens-Johnson syndrome). See section 2.
- stomach or intestinal bleeding, ulceration, or perforation: pass blood in your faeces (stools/motions), pass black tarry stools, vomit blood or dark particles that look like coffee grounds.

- liver disease (fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever) or abnormal liver function (abnormal test results continue or worsen), liver disease causing yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis).
- kidney disease or failure
- heart: water retention, high blood pressure, heart failure. Medicines such as Piroxicam may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke
- indigestion or heartburn. Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- inflamed pancreas (which may lead to severe pain in the upper abdomen or back)
- hallucinations (seeing or hearing things that are not there).

Common: may affect up to 1 in 10 people

- changes in the red blood cells which may result in unusual bruising or bleeding
- changes in the white blood cells which may result in increased risk of infection
- anorexia
- increase in blood sugar levels
- dizziness
- headache
- vertigo (a spinning sensation)
- drowsiness
- ringing in ears (tinnitus)
- abdominal pain/discomfort
- constipation
- diarrhoea
- wind
- feeling sick (nausea)
- being sick (vomiting)
- indigestion
- itching
- skin rash
- swelling of the feet, hands or other parts of the body (oedema)
- weight increase.

Uncommon: may affect up to 1 in 100 people

- blurred vision
- fast or pounding heartbeat
- sore mouth and/or lips
- decreased/low blood sugar level.

Rare: may affect up to 1 in 1,000 people

- kidney inflammation
- kidney damage
- change in urine output or appearance
- kidney pain or pain in abdomen.

Not known: frequency cannot be estimated from the available data

- abnormalities in the blood e.g. decreased haemoglobin
- fluid retention
- depression
- dream abnormalities
- changes in sleep patterns
- mental confusion
- mood alterations
- nervousness
- pins and needles
- eye irritations
- swollen eyes
- hearing impairment
- high blood pressure
- inflammation of the blood vessels

- shortness of breath
- constriction of the muscles lining the airways of lungs (bronchial)
- nose bleeds
- inflammation of the stomach lining (gastritis)
- stomach (peptic) ulcers.
- upset stomach
- hair loss
- rashes, blistering, peeling, itching, redness, tenderness, thickening or scaling of skin
- loosening or splitting of fingernails
- increased sensitivity of the skin to sunlight
- decreased fertility
- feeling unwell, general aches and pains
- weight decrease.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE PIXICAM CAPSULES

- Keep all medicines out of the reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.
- Store below 30°C, in a dry place.

Do not throw away any medicine 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. FURTHER INFORMATION

What Pixicam Capsules contains:

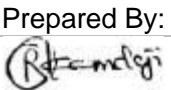

The active pharmaceutical ingredient is Piroxicam.

What Pixicam Capsules looks like and contents of the pack:

Pixicam capsules is presented as 1 x 10 and 10 x 10 capsules in sachets, placed in an outer carton with insert.

Supplier and Manufacturer

Fidson Healthcare Plc,
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