Piroxicam 10mg & 20mg Capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. What Piroxicam capsules are and what they are 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 affecting joints. Piroxicam 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 Piroxicam to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take Piroxicam capsules

Do not take Piroxicam capsules if you:

• previously had an allergic reaction to piroxicam (the active ingredient in this medicine) or any of the other ingredients of this medicine (listed in section 6); an allergic reaction to other NSAIDs or any other medications, especially 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 genitalia) 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 (infamed 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 apply 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 include: 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 week 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 this medicine.

• hallucinations (seeing or hearing things that are not there).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

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

• anaemia

• 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)

• ringing in ears (tinnitus)

• feeling unwell, general aches and pains

• weight decrease.

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 failure

• 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 eg. 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

• kidney inflammation possibly causing blood in the urine or pinkish urine, rashes, joint pain, breathing problems or tiredness

• 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

Report of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.yellowcard.gov.uk or search for Mhra Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

3. How to store Piroxicam capsules

Keep out of the sight and reach of children. Store below 25°C in a dry place. Protect from light. Do not take this medicine after the expiry date which is stated on the label/carton/bottle. 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.

4. Contents of the pack and other information

What Piroxicam capsules contain

• The active substance (the ingredient that makes the medicine work) is piroxicam. Each capsule contains either 10mg or 20mg of the active ingredient.

• The other ingredients are carmellose sodium, gelatin, lactose, magnesium stearate, maize starch, polysorbate, shellac, glaze, E127, E132 (10mg only), E171, E172 and propylene glycol.

What Piroxicam capsules look like and contents of the pack

Piroxicam 10mg capsules are pink and turquoise hard gelatin capsules printed “C” and the identifying letters “A” in black and are in pack sizes of 56.

Piroxicam 20mg capsules are pink hard gelatin capsules printed “C” and the identifying letters “B” in black and are in pack sizes of 28.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in July 2020.
Piroxicam 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. Other medicines and Piroxicam capsules Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even medicines you bought yourself 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; 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 with food and drink 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. Piroxicam capsules with food and drink could reduce the amount of Piroxicam that gets into your bloodstream, so its effect may be reduced. The maximum daily dose of Piroxicam capsules is 20 mg taken as one single daily dose. Piroxicam capsules should be taken with or after food. How to take Piroxicam capsules Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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. Piroxicam capsules should be taken with or after food. If you forget a dose Take special care with Piroxicam 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 missed dose. If you stop taking Piroxicam capsules If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects Like all medicines, this medicine 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, 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; • inflammation of the eye (iritis) or 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.

1. Black

2. Red

3. Blue

4. Green

5. Brown

6. Purple

German GTIN 14 (incorporating PZN): 75643525

Piroxicam at any time. If you develop a rash or any other skin symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine.

Take care with Piroxicam capsules Before prescribing Piroxicam capsules, 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 Piroxicam 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 Talk to your doctor or pharmacist before taking 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 have had any other medical problems or any allergies, or if you are not sure as to whether you can take 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 with food and drink 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. Piroxicam capsules should be taken with or after food. If you forget a dose Take special care with Piroxicam 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 missed dose. If you stop taking Piroxicam capsules If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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