

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PIXICAM® 20 (dispersible tablets)

Piroxicam 20 mg

Contains sugar (169 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking PIXICAM 20

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- PIXICAM 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet?

1. What PIXICAM 20 is and what it is used for
2. What you need to know before you take PIXICAM 20
3. How to take PIXICAM 20
4. Possible side effects
5. How to store PIXICAM 20
6. Contents of the pack and other information

1. What PIXICAM 20 is and what is it used for

Each dispersible tablet contains piroxicam 20 mg.

PIXICAM 20 is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

PIXICAM 20 is used to relieve some symptoms caused by osteoarthritis (arthrosis, degenerative 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 PIXICAM 20 to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take PIXICAM 20

Do not take PIXICAM 20

- If you are hypersensitive (allergic) to piroxicam, similar medicines called oxycams, or any of the other ingredients in PIXICAM 20. (Please see **What PIXICAM 20 contains.**)
- If you have blood formation disorders.
- If you have ever had an allergy to acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac or ibuprofen. Allergic reactions can include wheezing (asthma attacks), itchy runny nose, rashes or swelling of the skin.
- 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 that predispose to bleeding disorders 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, including COX-2 selective NSAIDs such as 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 a serious allergic reaction of any type to any medicine, especially skin reactions 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).

- If you previously had a skin reaction (regardless of severity) to piroxicam, other NSAIDs and other medications.
- If you have bleeding in your brain or other active bleeding or tend to have bleeding in general.
- If you have moderate to severe heart failure.
- If you have severe liver or kidney dysfunction.
- If you have pain after a bypass surgery (CABG).
- If you are in the last three months of your pregnancy.
- If you are a child or adolescent (or you treat a child or adolescent) under the age of 15 years.

Warnings and precautions

Take special care/Special care should be taken with PIXICAM 20

- If you have heart problems or high blood pressure.
- If you suffer from mild to moderate liver disease. You should not take PIXICAM 20 if you have severe liver dysfunction (see **Do not take PIXICAM 20**).
- If you suffer from mild to moderate kidney disease. You should not take PIXICAM 20 if you have severe kidney dysfunction (see **Do not take PIXICAM 20**).
- If you have certain blood formation disorders called “porphyria”.
- If you recently had major surgery.
- If you suffer from allergies, hay fever, asthma.

Your doctor may need to give you check-ups and will tell you how often you need to be checked during treatment with PIXICAM 20.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of PIXICAM 20, 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, and 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 PIXICAM 20, you must not take it ever again (see **Do not take PIXICAM 20**).

Other examples of serious, and sometimes life-threatening, skin rashes include exfoliative dermatitis (extreme shedding of the top layers of the skin), and fixed drug eruption (where the rash will reappear with re-exposure to the same medicine). If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Medicines such as PIXICAM 20 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. Do not exceed the recommended dose or duration of treatment. If you have or think you might be at risk for these diseases (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker), if you have heart problems or previously had a stroke, you should discuss your treatment with your doctor or pharmacist.

You should stop taking PIXICAM 20 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 PIXICAM 20 as, like all NSAIDs, PIXICAM 20 can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration, and perforation.

You should stop taking PIXICAM 20 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 PIXICAM 20 together with another medicine to protect your stomach and intestines from side effects (such as misoprostol or proton pump inhibitors), 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 acetylsalicylic acid to help prevent heart attacks or stroke.

With long-term use of painkillers, headaches can occur which cannot be treated with higher doses of the pain medicines. Ask your doctor for advice if you often suffer from headaches despite taking medicines to treat pain.

The habitual intake of analgesics, particularly combinations of different analgesic medicines, may cause permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

If you develop any visual complaints during treatment with PIXICAM 20, you should have an ophthalmic evaluation.

If you are taking PIXICAM 20 and are planning to become pregnant, especially if you have been experiencing difficulties conceiving or are undergoing investigation for infertility, talk to your doctor about possible withdrawal of PIXICAM 20 (see also **Pregnancy, breastfeeding, and fertility**).

Older people (over 70 years of age)

Older people have an increased risk of side effects to NSAIDs, especially bleeding in the stomach or intestines and perforation.

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 PIXICAM 20. Your doctor may prescribe PIXICAM 20 together with another medicine to protect your stomach and intestines from potential side effects (see above).

You should not take this medicine if you are older than 80 years.

Children and adolescents

Do not use PIXICAM 20 if you are below 15 years of age.

Other medicines and PIXICAM 20

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines must not be taken with PIXICAM 20:

- Acetylsalicylic acid (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 PIXICAM 20, if you are taking any of the following medicines:

- Corticosteroids, medicines given to treat a variety of conditions such as allergies, inflammation, and hormone imbalances
- Antiplatelet agents such as low dose acetylsalicylic acid (aspirin) to help prevent blood clotting and 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) (see **Warnings and precautions**)
- Antihypertensives to treat high blood pressure
- Methotrexate, which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis: the combination should be avoided
- Ciclosporin, used for prevention of transplant rejection, but also in the treatment of rheumatism
- Tacrolimus for the prevention of transplant rejection
- Diuretics (“water tablets”) such as hydrochlorothiazide to treat high blood pressure or kidney problems
- Potassium-sparing medicines, such as certain diuretics
- Probenecid, a medicine for gout
- Cimetidine, a medicine to reduce gastric acid

- Phenytoin, a medicine for epilepsy
- Cholestyramine, a medicine to lower cholesterol levels
- Oral antidiabetics such as glimepiride or glipizide, medicines to control elevated blood sugar levels: you should check your blood sugar levels more often
- Quinolone antibiotics, such as ciprofloxacin, moxifloxacin, or levofloxacin, for the treatment of bacterial infections
- Mifepristone for termination of pregnancy.

PIXICAM 20 with food and drink and alcohol

Consumption of alcohol should be avoided while taking PIXICAM 20 as it may intensify possible side effects, especially those affecting the gastrointestinal tract and the central nervous system.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Do not take PIXICAM 20 if you are in the last three months of pregnancy, as it can harm your baby.

Safety during pregnancy and lactation has not yet been established.

The active substance piroxicam is excreted in small amounts into breast milk. Use of PIXICAM 20 during breastfeeding is not recommended.

NSAIDs, such as PIXICAM 20, may interfere with the release of eggs from the ovaries (see **Warnings and precautions**).

Driving and using machinery

PIXICAM 20 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.

PIXICAM 20 contains sugar (lactose monohydrate)

PIXICAM 20 contains an ingredient called lactose (milk sugar). If you have lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking PIXICAM 20.

3. How to take PIXICAM 20

Do not share medicines prescribed for you with any other person.

Always take PIXICAM 20 exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of PIXICAM 20. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms in order to minimise potential side effects. Under no circumstances should you change your dose without first speaking to your doctor.

The tablets may be swallowed whole with adequate water or may be dispersed in a small quantity of water in a glass and the solution then swallowed.

Adults

The usual daily dose of PIXICAM 20 is 20 milligrams taken as one single daily dose.

The maximum daily dose is 40 mg (in single or divided doses) for the short-term treatment of acute muscle and bone conditions or acute gout.

Older people

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

Your doctor will tell you how long your treatment with PIXICAM 20 will last. If you have the impression that the effect of PIXICAM 20 is too strong or too weak, tell your doctor or pharmacist.

If you take more PIXICAM 20 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include headache, dizziness, drowsiness, stomach pain, nausea, vomiting and hyperventilation.

If you forget to take PIXICAM 20

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 the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PIXICAM 20 can have side effects.

Not all side effects reported for PIXICAM 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

Tell your doctor immediately and stop taking PIXICAM 20 if you experience any of the following symptoms after taking this medicine:

- Any sign of bleeding in the stomach or intestines, such as passing black (tarry) 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)
- Potentially life-threatening skin rashes including peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or extensive peeling of the skin (toxic epidermal necrolysis) (see **Warnings and precautions**)

- Yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems.

Other side effects that may be experienced while taking this medicine are:

Frequent side effects:

- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- High levels of a specific type of white blood cell (eosinophilia)
- Changes in white blood cell counts which may result in an increased risk of infection (leukopenia), or thrombocytopenia (reduction in blood platelets) which increases the risk of bleeding or bruising
- Loss of appetite
- Increase in blood sugar levels
- Dizziness, headache, sleepiness
- A feeling of dizziness or “spinning”
- Ringing in ears (tinnitus)
- Stomach pain/discomfort, constipation
- Diarrhoea, wind, feeling sick (nausea), vomiting, indigestion
- Itching, skin rash
- Swelling of the ankles, feet or fingers (oedema)
- Increase in liver enzymes
- Abnormal kidney function test results
- Weight increase.

Less-frequent side effects:

- Decreased/low blood sugar level which may cause faintness, hunger, sweating or jitteriness
- Blurred vision
- Feeling your heartbeat

- Sore mouth and/or lips.

Not known - frequency cannot be estimated from the available data

- Abnormalities in the blood such as severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Fluid retention
- Depression, dream abnormalities, hallucinations, difficulty in sleeping, mental confusion, mood alterations, nervousness
- Tingling or numbness (paraesthesia)
- Eye irritation, swollen eyes
- Difficulty hearing
- Heart failure with signs such as breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- Inflammation of the blood vessels
- High blood pressure
- Forming of blood clots in blood vessels: heart attack (myocardial infarction) or stroke
- Difficulty in breathing or wheezing
- Nosebleed
- Inflammation of the stomach lining (gastritis)
- Inflammation of the pancreas (which may lead to severe pain in the upper abdomen or back)
- Gastrointestinal ulcers and/or perforation
- Worsening of colitis and Crohn's disease
- Ulcers in the mouth
- Inflammation of the liver (fatal hepatitis)
- Hair loss

- Allergic reaction involving purple spots on the skin, joint pain, abdominal pain and kidney dysfunction (Henoch-Schoenlein purpura)
- Loosening or splitting of fingernails
- Increased sensitivity of the skin to sunlight
- Kidney disease, kidney inflammation, kidney failure
- Decreased fertility of women
- Generally feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PIXICAM 20

5. How to store PIXICAM 20

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Do not use the tablets after the expiry date printed on the container, blister, or label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PIXICAM 20 contains

The active substance is piroxicam.

The other ingredients are colloidal silica anhydrous, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium dodecyl sulphate.

What PIXICAM 20 looks like and contents of the pack

PIXICAM 20 is a uniform white to light yellow round, biconvex 9 mm x 4 mm tablet with a score notch.

PIXICAM 20 is available in white HDPE securitainers or polypropylene foil blisters in packs of 30 and 100 dispersible tablets.

Holder of the Certificate of Registration

Kiara Health (Pty) Ltd

72 Steel Road

Spartan

Kempton Park

1619

South Africa

This leaflet was last revised on

08 May 2023

Registration Number

29/3.1/0752

Additional countries registration details:

<i>Country</i>	<i>Product name</i>	<i>Scheduling status (or Category of distribution)</i>	<i>Registration number</i>
Namibia	PIXICAM® 20	NS2	04/3.1/1348
Botswana	PIXICAM® 20	S2	BOT1703203
Mauritius	PIXICAM® 20		R2930/02/14
Zambia	PIXICAM® 20		039/045

Name and address of manufacturer:

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Germany