1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

XYCAM-20 mg capsules

Piroxicam

Contains sugar: Lactose monohydrate 264,70 mg

Read all of this leaflet carefully before you start taking XYCAM-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.
- XYCAM-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 XYCAM-20 is and what it is used for
2. What you need to know before you take XYCAM-20
3. How to take XYCAM-20
4. Possible side effects
5. How to store XYCAM-20
6. Contents of the pack and other information

1. What XYCAM-20 is and what it is used for

XYCAM-20 belongs to a group of medicines called non-steroidal anti-inflammatory

medicines (NSAIDs). This means it will help to relieve pain and reduce swelling affecting joints.

XYCAM-20 is used to relieve:

- Symptoms caused by joint disease (osteoarthritis) and rheumatism of the spine (rheumatoid arthritis and ankylosing spondylitis), such as swelling, stiffness and joint pain.
- Severe pain, redness and tenderness in joints (gout).
- Symptoms related to disorders of the muscles, nerves, tendons, joints, cartilage, and spinal discs (acute musculoskeletal disorders).

XYCAM-20 does not cure arthritis and will help you only as long as you continue to take it.

2. What you need to know before you take XYCAM-20

Do not take XYCAM-20:

- if you are hypersensitive (allergic) to piroxicam or any of the other ingredients of XYCAM-20 (listed in section 6).
- if you have history of skin reaction (regardless of severity) to XYCAM-20 or other NSAIDs.
- if you have previously had or currently have a stomach or intestinal perforation, ulceration or bleeding, with or without previous NSAID use.
- 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), 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 have severe heart failure, liver disease, or porphyria.
- if you are a child.
- if you are pregnant or breastfeeding.
- if you are pregnant, do not use XYCAM-20 at 20 weeks or later in pregnancy, unless specifically advised to do so by your health care professional, because these medicines may cause harm in your unborn baby.
- if you suffer from asthma, nasal polyps, angioedema, rhinitis or urticaria when you use aspirin or other NSAIDs.

Warnings and precautions

Take special care with XYCAM-20:

- if you have heart problems, as XYCAM-20 may be associated with an increased risk of heart attack (myocardial infarction) or stroke. The 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.
- XYCAM-20 may cause fluid retention and oedema which may worsen heart conditions.
- 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; asthma; diabetes; high cholesterol.
- if you have or had any other medical problems or any allergies or if you are not sure as to whether you can use XYCAM-20 tell your doctor before taking this medicine.
- if you have any allergic reaction such as a skin rash, swelling of the face, wheezing or difficulty breathing, you should stop taking XYCAM-20 immediately and tell your doctor. Serious skin reactions, some of them fatal,

have been reported. If you develop a skin rash, fever or swelling of lymph nodes, this could be Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). If you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

- if you have stomach pain, perforation, ulceration and bleeding as XYCAM-20 can cause serious reactions in the stomach and intestines. Administration of doses greater that 20 mg per day carries an increased risk of these side effects.
- The possible need for combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should be carefully considered.
- 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, you should stop taking XYCAM-20 immediately and tell your doctor.
- if you are taking antidepressants, such as selective serotonin reuptake inhibitors (SSRIs); antiplatelet medication, such as aspirin; anti-inflammatories (NSAIDs including COX-2 inhibitors) and if you drink large amounts of alcohol, you are at increased risk of stomach related (gastrointestinal) side effects.
- if you have adverse eye reactions with XYCAM-20, you should have ophthalmic evaluation.
- if you are taking anticoagulants such as warfarin. XYCAM-20 decreases platelet aggregation and prolongs bleeding time.
- if you are known or suspected to be a poor Cytochrome P450 family 2 subfamily C member 9 (CYP2C9) metabolizer based on previous history/experience with other CYP2C9 substrates, you should take XYCAM-

20 with caution.

- if you are 30 weeks or later in your pregnancy, since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.

Undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms.

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 XYCAM-20 as you are at higher risk of complications.
- If you are over 80 years of age, you should avoid taking XYCAM-20.

Children

Not for use in children

Other medicines and XYCAM-20

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

Tell your doctor if you are taking any of the following:

- Corticosteroids, which are medicines given to treat a variety of conditions such as allergies and hormone imbalances.
- Antiplatelets, such as low dose aspirin used 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 selective serotonin re-uptake inhibitors (SSRIs).
- Certain medicines used for psychiatric conditions such as lithium.
- Antihypertensives used to treat high blood pressure. NSAIDs including XYCAM-20 can reduce the efficacy of diuretics and other anti-hypertensive medicines.
- 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.
- Cimetidine, a medicine used to treat heartburn and peptic ulcers, may cause slight increase in absorption of piroxicam. The small increase in absorption is unlikely to be clinically significant.
- Highly protein-bound medicines. XYCAM-20 is highly protein-bound and therefore might be expected to displace other protein-bound medicines.
- Antidiabetic medicines. XYCAM-20 can increase the hypoglycaemic effect of antidiabetic medicines.
- Other NSAIDS. Use of two or more NSAIDs at the same time could result in an increase in side effects.
- Anticoagulants, such as warfarin used to prevent blood clots.

XYCAM-20 with food and drink

XYCAM-20 should be taken with or after food.

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 provider for advice before taking this medicine.

You should not use XYCAM-20 at 20 weeks or later during your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.

XYCAM-20 is not recommended if you are pregnant or breastfeeding your infant as safety has not been established.

XYCAM-20 is not recommended if you are planning to have a baby. The use of XYCAM-20 may impair female fertility.

Driving and using machines

XYCAM-20 can cause you to feel dizzy, drowsy, tired or have problems with your vision.

If you are affected, do not drive or operate machinery.

It is not always possible to predict to what extent XYCAM-20 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which XYCAM-20 affects you (see section 4).

XYCAM-20 contains lactose

XYCAM-20 contains lactose, a type of sugar, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have rare hereditary conditions of lactose/fructose or galactose intolerance,

you should not take XYCAM-20.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this XYCAM-20.

3. How to take XYCAM-20

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

Always take XYCAM-20 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis:

The usual dose of XYCAM-20 is 20 mg (1 capsule) daily.

Long term administration of doses higher than 30 mg carries an increased risk of gastrointestinal side effects.

Acute musculoskeletal disorders:

An initial dose of 40 mg (2 capsules) daily may be given for the first two days in single or divided doses. For the remainder of the 7 to 14 day treatment period, the dose should be reduced to 20 mg (1 capsule) daily.

Acute gout:

The usual dose is 40 mg (2 capsules) daily for 5 to 7 days.

XYCAM-20 is not indicated for the long-term management of gout.

Special populations

Elderly population

In elderly patients it may be necessary to reduce the dosage and limit the duration of treatment.

For oral administration.

XYCAM-20 should be taken with a full glass (240 ml) of water and you should remain in an upright position for 15 to 30 minutes after administration.

Your doctor will tell you how long your treatment with XYCAM-20 will last. Do not stop treatment early. If you have the impression that the effect of XYCAM-20 is too strong or too weak, tell your doctor or pharmacist.

If you take more XYCAM-20 than you should

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

Always take the labelled medicine package with you, whether there is any XYCAM-20 left or not.

If you forget to take XYCAM-20

Do not take a double dose to make up for forgotten individual doses.

Take your missed dose as soon as you remember, if within a few hours after missing a dose. However, if it is nearly time for the next dose, skip the missed dose.

If you have forgotten to take several doses, contact your doctor without delay.

If you have any further questions on how to take XYCAM-20, ask your doctor or pharmacist.

4. Possible side effects

XYCAM-20 can have side effects.

Not all side effects reported for XYCAM-20 are included in this leaflet. Should your

general health worsen or if you experience any untoward effects while taking XYCAM-20, please consult your healthcare provider for advice.

If any of the following happens, stop taking XYCAM-20 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN), Severe Cutaneous Adverse Reactions (SCARS), Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS), Fixed Drug Eruption (FDE).

These are all very serious side effects. If you have them, you may have had a serious reaction to XYCAM-20. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Effects on blood and medical tests: abnormalities in blood and other biochemical tests. These effects may result in unusual bruising or bleeding or increased risk of infection (anaemia, eosinophilia, leukopenia thrombocytopenia),
- sudden wheeziness, difficulty in breathing (bronchospasm),
- effects on your heart and circulation: fast or pounding heartbeat (palpitations), high blood pressure (hypertension), swollen ankles and/or feet

(oedema). Medicines such as XYCAM-20 may be associated with a small increased risk of heart attack (myocardial infarction) or stroke,

- any sign of bleeding in the stomach or intestines (gastrointestinal bleeding or haemorrhage), such as passing black or bloodstained bowel movements (melena) or vomiting blood (haematemesis),
- stomach ulcers or inflammation of your stomach (peptic ulceration, colitis and Crohn's disease),
- yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems. Liver enzymes may be increased,
- effects on your kidneys: kidney inflammation, kidney failure or kidney damage. If you notice any change in your urine output or appearance, possibly accompanied by kidney pain, or pain in your abdomen or back contact your doctor.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea or constipation, wind,
- feeling sick (nausea), vomiting, loss of appetite (anorexia),
- stomach ache, indigestion, abdominal pain/stomach discomfort,
- high blood sugar levels (hyperglycaemia),
- dizziness, headache, unusual weakness or tiredness without any other symptoms (somnolence), spinning sensation (vertigo),
- ringing in ears (tinnitus),
- effects on your skin: rashes, itching.

Less frequent side effects:

- Effects on your eyes, blurred vision,

- sore mouth and/or lips (stomatitis),
- low blood sugar levels (hypoglycaemia).

Side effects with an unknown frequency:

- Stomach lining inflammation (gastritis),
- mood alterations, abnormal dreams, mental confusion, depression, seeing things that are not there (hallucination), sleeplessness (insomnia), nervousness, feeling of pins and needles (paraesthesia),
- effects on your skin: redness, tenderness, thickening or scaling of skin (angioedema, dermatitis exfoliative), loosening or splitting of fingernails (onycholysis), hair loss (alopecia) and increased sensitivity of the skin to sunlight (photosensitivity reactions), red or purple skin discoloration (purpura),
- other effects: fever, nosebleeds, inflamed pancreas (which may lead to severe pain in the upper abdomen or back), feeling unwell (malaise),
- effects on eyes or ears: swollen eyes and eye irritation, hearing impairment,
- bladder disorders,
- decreased female fertility,
- inflammation of the blood vessels (vasculitis),
- weight increase or decrease, fluid retention.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of XYCAM-20.

5. How to store XYCAM-20

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XYCAM-20 contains

The active substance is 20 mg of piroxicam.

The other ingredients are black oxide (C.I. 77499), croscarmellose sodium, dimethicone, gelatin, lactose monohydrate, red oxide (C.I. 77491), shellac, sodium lauryl sulphate, starch (maize dried), titanium dioxide (C.I. 77891).

Contains sugar: Lactose monohydrate 264,70 mg

What XYCAM-20 looks like and contents of the pack

XYCAM-20 is a white to slight yellow powder encapsulated within a size “2” hard gelatin capsule with opaque brown cap and body printed “XYCAM 20” on the body with white ink.

30 capsules are packed into a clear, polyvinyl chloride (PVC) blister strip and sealed with a silver, aluminium foil backing.

30 capsules are packed into a round, white, opaque, high-density polyethylene container and sealed with a white, opaque, polypropylene, child-resistant screwcap with a transparent induction seal liner.

30 capsules are packed into a white, opaque, polyethylene minibag with a rib structure seal.

30 or 500 capsules are packed into a cylindrical, white, polypropylene container and sealed with a white, low-density polyethylene cap.

30 or 500 capsules are packed into a round, white, high-density polyethylene container and sealed with a white, opaque, polypropylene, screw cap with an induction wad.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

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Namibia: NS2 90/3.1/001273

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