1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

XYCAM DISPERSIBLE TABLETS 20 mg

Piroxicam

Contains sugar: Lactose monohydrate 331,50 mg

Read all of this leaflet carefully before you start taking XYCAM DISPERSIBLE TABLETS

- 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 DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS is and what it is used for
2. What you need to know before you take XYCAM DISPERSIBLE TABLETS
3. How to take XYCAM DISPERSIBLE TABLETS

4. Possible side effects
5. How to store XYCAM DISPERSIBLE TABLETS
6. Contents of the pack and other information

1. What XYCAM DISPERSIBLE TABLETS is and what it is used for

XYCAM DISPERSIBLE TABLETS belong 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 DISPERSIBLE TABLETS are used to relieve:

- Symptoms such as swelling, stiffness and joint pain caused by joint disease and rheumatism of the spine (osteoarthritis, rheumatoid arthritis and ankylosing spondylitis). XYCAM DISPERSIBLE TABLETS do not cure arthritis and will help you only as long as you continue to take it.
- 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).

2. What you need to know before you take XYCAM DISPERSIBLE TABLETS

Do not take XYCAM DISPERSIBLE TABLETS:

- if you are hypersensitive (allergic) to piroxicam or any of the other ingredients of XYCAM DISPERSIBLE TABLETS (listed in section 6),
- if you have had a previous skin reaction (regardless of severity) to

XYCAM DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS:

- if you are at risk of developing a heart attack or stroke. Medicines such as XYCAM DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS 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 and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophillia 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 pain, perforation, ulceration and bleeding in the stomach and intestines as XYCAM DISPERSIBLE TABLETS can cause serious reactions in the stomach and intestines. Administration of doses greater

than 20 mg per day carries an increased risk of these side effects.

- the possible need for combination therapy with gastro-protective medicines (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 DISPERSIBLE TABLETS immediately and tell your doctor.
- If you are taking oral corticosteroids, antidepressants such as, selective serotonin reuptake inhibitors (SSRIs), anti-platelet medicines such as low-dose acetylsalicylic acid such as, aspirin; and if you drink large amounts of alcohol, you are at an increased risk of stomach-related (gastrointestinal) side effects.
- If you have adverse eye reactions with XYCAM DISPERSIBLE TABLETS, you should have ophthalmic evaluation.
- 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 DISPERSIBLE TABLETS 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.

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 DISPERSIBLE TABLETS, as you are at higher risk of complications.

- If you are over 80 years old, you should avoid taking XYCAM DISPERSIBLE TABLETS.

Children

Not for use in children.

Other medicines and XYCAM DISPERSIBLE TABLETS

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.
- Antiplatelet 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 such as lithium for psychiatric conditions.
- Antihypertensives used 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.
- 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 DISPERSIBLE TABLETS is highly protein-bound and therefore might be expected to displace other protein-bound medicines.
- Anticoagulants, such as warfarin, used to prevent blood clots.
- NSAIDs. Use of two or more NSAIDs at the same time could result in an increase in side effects.
- Antidiabetic medicines. XYCAM DISPERSIBLE TABLETS can potentiate the hypoglycaemic effect of antidiabetic medicines.

XYCAM DISPERSIBLE TABLETS with food and drink

XYCAM DISPERSIBLE TABLETS 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 XYCAM DISPERSIBLE TABLETS.

You should not take XYCAM DISPERSIBLE TABLETS if you are over 20 weeks pregnant as it can have an effect on the unborn baby. It is not usually recommended at other stages of pregnancy.

XYCAM DISPERSIBLE TABLETS is not recommended if you are breastfeeding your infant as safety has not been established.

The use of XYCAM DISPERSIBLE TABLETS may impair female fertility.

Driving and using machines

XYCAM DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS affects you (see section 4).

XYCAM DISPERSIBLE TABLETS contains lactose

XYCAM DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS.

If you have been told by your doctor that you have an intolerance to some

sugars, contact your doctor before taking XYCAM DISPERSIBLE TABLETS.

3. How to take XYCAM DISPERSIBLE TABLETS

Do not share medicines prescribed for you with any other person.
Always take XYCAM DISPERSIBLE TABLETS 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, osteo-arthritis, ankylosing spondylitis:
The usual dose of XYCAM DISPERSIBLE TABLETS is 20 mg (1 tablet) daily in single dose.
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 tablets) 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 daily.

Acute gout:
The usual dose is 40 mg (2 tablets) daily for 5 to 7 days.
XYCAM DISPERSIBLE TABLETS are not indicated for the long-term

management of gout.

For oral administration.

XYCAM DISPERSIBLE TABLETS 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.

XYCAM DISPERSABLE TABLETS may be taken whole with fluid or dispersed in a minimum of 50 ml water and then swallowed.

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

If you take more XYCAM DISPERSIBLE TABLETS 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 DISPERSIBLE TABLETS left or not.

If you forget to take XYCAM DISPERSIBLE TABLETS

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

If you have missed a dose of XYCAM DISPERSIBLE TABLETS, take the dose that you have missed as soon as you remember. 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 DISPERSIBLE TABLETS, ask your doctor or pharmacist.

4. Possible side effects

XYCAM DISPERSIBLE TABLETS can have side effects.
Not all side effects reported for XYCAM DISPERSIBLE TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XYCAM DISPERSIBLE TABLETS, please consult your healthcare provider for advice.
If any of the following happens, stop taking XYCAM DISPERSIBLE TABLETS 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 Rash with Eosinophilia and Systemic Symptoms (DRESS) syndrome, Fixed Drug Eruption (FDE), dermatitis exfoliative, erythema multiforme.

These are all very serious side effects. If you have them, you may have had a serious reaction to XYCAM DISPERSIBLE TABLETS. 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, shortness of breath (bronchospasm, dyspnoea),
- effects on your heart and circulation: fast or pounding heartbeat, high blood pressure (hypertension), swollen ankles and/or feet (oedema). Medicines such as XYCAM DISPERSIBLE TABLETS 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),
- peptic ulceration, exacerbation of 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 or increase in liver

enzymes,

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

Less frequent side effects:

- Effects on your eyes: blurred vision,
- changes in blood sugar levels may also occur: low blood sugar

(hypoglycaemia),

- sore mouth and/or lips (stomatitis).

Side effects with an unknown frequency:

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

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:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store XYCAM DISPERSIBLE TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep in the 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 DISPERSIBLE TABLETS contains

The active substance is 20 mg of piroxicam.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, purified talc, sodium lauryl sulphate.

Contains sugar: Lactose monohydrate 331,50 mg

What XYCAM DISPERSIBLE TABLETS look like and contents of the pack

XYCAM DISPERSIBLE TABLETS are white, oblong, biconvex tablets engraved with “XYCAM” on one side and plain on the other side.

30 tablets are packed into a white, cylindrical, polypropylene container together with a white, round foam insert, white, round, polypropylene desiccant disc and sealed with a white, round, low-density polyethylene tamper evident closure.

30 tablets are packed into a white, round, high-density polyethylene container and sealed with a white, opaque polypropylene screw cap with an induction liner.

30 tablets are packed into a clear polyvinylchloride film and sealed with a silver, aluminium foil backing. The blister strips are packed into an outer cardboard carton with a leaflet.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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This leaflet was last revised in

13 November 2023

Registration number

Y/3.1/227

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

Tel: 0800 118 088

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