Patient Information Leaflet

SCHEDULING STATUS

S3

PYROCAPS 20 mg Capsules

Piroxicam

Contains Sugar: Lactose 214 mg per capsule

Read all of this leaflet carefully before you start taking PYROCAPS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **PYROCAPS** 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 **PYROCAPS** is and what it is used for
2. What you need to know before you take **PYROCAPS**
3. How to take **PYROCAPS**
4. Possible side effects
5. How to store **PYROCAPS**
6. Contents of the pack and other information

1. What PYROCAPS is and what it is used for

PYROCAPS contains piroxicam which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Piroxicam contains properties for the management of pain, inflammation and fever.

PYROCAPS are used for the treatment of:

- Inflammatory disease of the joints (rheumatoid arthritis)
- wear and tear of joints (osteo-arthritis)
- progressive stiffening of the spine (ankylosing spondylitis)
- injuries or pain in the human musculoskeletal system, including the joints, ligaments, muscles, nerves, tendons, and the structures that support the limbs, neck and back. (acute musculoskeletal disorders)
- Arthritis caused by the formation of uric acid crystals in the joints. (Gout)

2. What you need to know before you take PYROCAPS

Do not take **PYROCAPS**

- If you are hypersensitive (allergic) to piroxicam or any of the other ingredients of **PYROCAPS** (see section 6).
- are suffering from liver problems (hepatic dysfunction)
- if you have a history of stomach problems such as ulcers, Crohn's disease, stomach cancers and inflammation/infections of the intestines.
- are suffering from internal bleeding of the stomach or intestines (gastro-intestinal haemorrhage)
- take aspirin and other non-steroidal anti-inflammatory medicines which cause symptoms of asthma, inflamed mucous membrane of the nose or raised red itchy areas of the skin.
- pregnant or breastfeeding
- under 12 years of age
- take anticoagulants (medicines that prevent blood clotting)
- if you had a previous serious allergic medicine reactions of any type, especially skin eruptions such as skin immune reaction (redness, rash), Steven-Johnson syndrome and toxic epidermal necrolysis.

- If you suffer from severe heart failure
- If you are pregnant and in the last trimester of your pregnancy
- If you are pregnant, do not use **PYROCAPS** 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.

Warnings and precautions

Tell your doctor before taking **PYROCAPS**:

Take special care with **PYROCAPS** if you:

- suffer from liver problems
- suffer from kidney problems
- have diabetes
- suffer from internal bleeding of the stomach or intestines
- suffer from stomach ulcers
- suffer from asthma
- suffer from high blood pressure or any other heart diseases
- are unable to take aspirin or any other NSAIDS
- are pregnant or breastfeeding
- are under 12 years of age
- are on medication that prevents blood clotting
- suffer from a blood platelet condition
- suffer from decreased red/white blood cell count
- suffer from a condition of bleeding in the skin (purpura)
- have been taking **PYROCAPS** for prolonged period of time or if you suddenly stop taking these tablets

- suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)
- are a female trying to have a baby or have any history of fertility problems
- are 30 weeks or later in 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
- If you develop a skin rash, fever, swelling of lymph nodes and and an increase of eosinophils (a type of white blood cells). This is known as 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.

Children and adolescents

Do not give **PYROCAPS** to children under 12 years of age.

Other medicines and PYROCAPS

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using:

- anti-coagulants (medicines that prevent blood clotting)
- anti-platelets (medicines that prevent blood platelets from sticking together and forming clots)
- anti-depressants (medicines to treat mood disorders)
- corticosteroids
- aspirin or any other Non-steroidal anti-inflammatory drugs (NSAIDs)
- heart medication
- ciclosporin (used to prevent organ rejection after a transplant)

- tacrolimus
- cimetidine
- Digoxin
- Digitoxin
- Diuretics (water medication)
- Lithium
- Antibiotics
- Mifepristone
- Methotrexate

PYROCAPS with food, drink and alcohol

See section 3.

Pregnancy, breast-feeding 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 health care provider for advice before taking **PYROCAPS**.

Do not use **PYROCAPS** at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

Additionally do not use **PYROCAPS** at 30 weeks or later in 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.

Breast-feeding

You should not use **PYROCAPS** if you are breastfeeding.

Driving and using machines

The use of **PYROCAPS** may cause drowsiness, dizziness, fatigue and impaired sight. If you experience any of them, caution should be exercised in carrying out activities that require alertness.

PYROCAPS contains Lactose

PYROCAPS contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **PYROCAPS**.

3. How to take PYROCAPS

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

Always take **PYROCAPS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Rheumatoid arthritis, osteo-arthritis, ankylosing spondylitis:

The usual daily dose is 20 mg (one capsule) given in a single dose. Long-term administration of doses higher than 30 mg carries an increased risk of gastrointestinal (stomach and intestines) side effects.

Acute musculoskeletal disorders:

40 mg (two capsules) initially for the first two days given in single or divided doses, thereafter, 20 mg (one capsule) for the remainder of the seven to fourteen day period.

Acute Gout:

Therapy should be initiated by a single oral dose of 40 mg (two capsules) followed on the next four to six days by 40 mg (two capsules) given in a single or divided dosage. Pyrocaps® is not indicated for the long-term management of gout

Your doctor will tell you how long your treatment with **PYROCAPS** will last. Do not stop treatment early because you feel better. If you have the impression that the effect of **PYROCAPS** is too strong or too weak, tell your doctor or pharmacist.

If you take more PYROCAPS® CAPSULES than you should:

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

Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

If you forget to take PYROCAPS:

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose to make up for forgotten individual doses. You should contact your doctor on how to proceed.

4. Possible side effects

PYROCAPS can have side effects.

Not all side effects reported for **PYROCAPS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this **PYROCAPS**, please consult your health care provider for advice. If any of the following happens, stop taking

PYROCAPS ® CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Extremely serious allergic skin reaction, rash, itching of the skin (Steven-Johnson Syndrome and toxic epidermal necrolysis)
- Stomach or intestinal ulcers with bleeding
- Prolonged bleeding time
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- Fixed drug eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

These are all very serious side effects. If you have them, 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:

- Swelling/fluid buildup especially in the ankles

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

Tell your doctor if you notice any of the following:

- ringing in the ears
- dizziness
- headache
- drowsiness
- blurred vision
- decreased red blood cell count

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. This includes any possible side effects not listed in this leaflet. 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 effect you can help provide more information on the safety of **PYROCAPS**.

5. How to store PYROCAPS

- Store all medicines out of reach of children.
- Store at or below 25 ^{0}C
- Store in the original package / container
- Protect from light
- Do not use after the expiry date stated on the label / carton / ampoule
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PYROCAPS contains

Each capsule contains 20 mg Piroxicam.

The other ingredients are: Lactose 200 mesh (fast flow), maize, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, starch

What PYROCAPS looks like and the contents of the pack

Capsules with an opaque white body and opaque maroon cap.

Bottles of 30 capsules.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

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