PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PIROFEN 20 Capsules

Piroxicam

Contains tartrazine

Contains sugar: Each capsule contains lactose (189,90 mg) and mannitol (40 mg)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PIROFEN 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 PIROFEN 20 is and what it is used for
2. What you need to know before you take PIROFEN 20
3. How to take PIROFEN 20
4. Possible side effects
5. How to store PIROFEN 20
6. Contents of the pack and other information

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

PIROFEN 20 belongs to a group of pain killers called Non-Steroidal Anti-Inflammatory medicines (NSAIDs) and is used to relieve symptoms of pain, fever and inflammation.

PIROFEN 20 is 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 PIROFEN 20

Do not take PIROFEN 20 if:

- You are hypersensitive (allergic) to piroxicam or any of the other ingredients of PIROFEN 20 (listed in section 6);
- You are hypersensitive (allergic) to aspirin or other NSAIDs, or have experienced previous allergic symptoms such as swelling, difficulty breathing, hay fever or rashes when aspirin or NSAIDs were taken;
- You have liver problems (hepatic dysfunction);
- You have a peptic ulcer (ulcer in your stomach or stomach lining) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation;
- You are pregnant and in the last trimester of your pregnancy or breastfeeding;
- You should not take PIROFEN 20 if you are pregnant as there is a risk of kidney failure to your unborn baby;

- If you 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;
- You should not take PIROFEN 20 with coumarin type anticoagulants (blood thinners), e.g., warfarin.
- You have a history of stomach problems such as ulcers, Crohn's disease, stomach cancers and inflammation/infections of the intestines.
- 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.
- You suffer from severe heart failure.
- You are under 12 years of age.

Warnings and precautions

Special care should be taken with PIROFEN 20:

- If you have any kidney problems;
- If you have any liver problems;
- PIROFEN 20 decreases platelet aggregation and prolongs bleeding time. This is important if you have coagulation (clotting) disorders;
- If you have diabetes;
- If you suffer from internal bleeding of the stomach or intestines;
- If you suffer from stomach ulcers;
- If you suffer from asthma;
- If you suffer from high blood pressure or any other heart diseases;
- If you are unable to take aspirin or any other NSAIDs;
- If you suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN);
- If you are a female trying to have a baby or have any history of fertility problems;

- If you develop a skin rash, fever, swelling of lymph nodes 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.
- If you develop any problems with your eyes, it is recommended that you go and have your eyes tested.

Children

Use in children: PIROFEN 20 is not recommended for children under 12 years of age.

Other medicines and PIROFEN 20

Always tell your health care provider if you are taking any other medicine. (This includes all 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 (medicines to treat a variety of conditions such as allergies and hormone imbalances)
- aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs)
- antihypertensives (medicines to treat high blood pressure)
- ciclosporin (used to prevent organ rejection after a transplant)
- tacrolimus (used to suppress the immune system after organ transplant)
- cimetidine (used in the treatment of heartburn and peptic ulcers)
- digoxin and digitoxin (medicines used to treat heart conditions)

- diuretics (water medication)
- lithium (medicine for depression)
- antibiotics (medicines used to treat various infections)
- mifepristone (used to medically terminate pregnancies)
- methotrexate (medicine to treat various conditions such as cancers, psoriasis and rheumatoid arthritis)

PIROFEN 20 with food, drink and alcohol

Caution should be taken not to ingest this medicine with excessive amounts of alcohol as it can lead to serious complications.

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 health care provider for advice before taking PIROFEN 20.

Do not use PIROFEN 20 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 PIROFEN 20 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.

Breastfeeding

You should not use PIROFEN 20 if you are breastfeeding.

Driving and using machines

The use of PIROFEN 20 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.

It is not always possible to predict to what extent PIROFEN 20 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PIROFEN 20 affects them.

PIROFEN 20 contains FD&C yellow no. 5 (Tartrazine)

It may cause allergic type reactions including difficulty breathing. This is frequently seen in patients who also have aspirin sensitivity.

PIROFEN 20 contains lactose

PIROFEN 20 contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take PIROFEN 20.

3. How to take PIROFEN 20

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

Always take PIROFEN 20 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. PIROFEN 20 is not indicated for the long-term management of gout.

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

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

If you forget to take PIROFEN 20

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.

4. Possible side effects

PIROFEN 20 can have side effects.

Not all side effects reported for PIROFEN 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PIROFEN 20, please consult your health care provider for advice.

If any of the following happens, stop taking PIROFEN 20 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 have had a serious reaction to PIROFEN 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:

- 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:

Frequent

- Dizziness;
- Headache;
- Sleepiness;
- Vertigo (feeling of spinning);
- Conditions affecting red and white blood cell counts;

- Serious eating disorder (anorexia);
- High blood sugar levels;
- Ringing in the ears;
- Decreased red blood cell count;
- Stomach pain or discomfort; constipation, diarrhoea, passing wind;
- Nausea (feeling sick), vomiting (being sick);
- Indigestion;
- Itchiness, skin rash;
- Increased liver enzymes;
- Weight gain.

Less frequent

- Low blood sugar levels;
- Blurred vision;
- Abnormal heartbeat;
- Inflammation of the mouth;
- Problems with your kidneys, kidney failure.

Frequency unknown

- A rare disease condition in which the bone marrow does not produce adequate number of new blood cells;
- Depression;
- Abnormal dreams, hallucinations;
- Inability to sleep;
- Mental confusion, altered moods, nervousness;
- Tingling or numbness in the limbs;
- Eye irritations, swollen eyes;

- Hearing impairment;
- Heart failure; arterial thrombotic events (such as stroke or heart attack);
- Inflammation of the arteries;
- High blood pressure;
- Swelling or irritation of the airways (bronchospasm), shortness of breath;
- Nosebleed;
- Inflammation of the stomach;
- Stomach or intestinal bleeding (pass blood in your stools, pass black tarry stools, vomit blood or dark particles that look like coffee grounds);
- Inflammation of the pancreas;
- Inflammation of the liver (that can lead to death);
- Yellowing of the skin (jaundice);
- Loss of hair;
- Different types of skin reactions;
- Kidney disease;
- Decreased female fertility;
- Not feeling well;
- Weight loss;
- Your body is not producing enough red blood cells.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store PIROFEN 20

Store all medicines out of reach of children.

- Store in a dry place at or below 25 °C. Protect from light.
- 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 PIROFEN 20 contains

- The active substance is piroxicam. Each capsule contains piroxicam 20 mg.
- The other ingredients are:

  Capsule content: Lactose, mannitol, polysorbate 80, colloidal silicon dioxide, magnesium stearate

  Capsule shell: Brilliant blue, tartrazine, carmoisine, erythrosine, titanium dioxide, gelatin

What PIROFEN 20 looks like and contents of the pack

PIROFEN 20 capsules are light blue/dark blue, size '2', locked hard gelatin capsules containing off-white to light-tan or light-yellow powder. Shells are opaque.

PIROFEN 20 will be packed in Alu-PVC blister packs.

5 Blisters of 20 capsules per carton (i.e., 100 capsules).

Holder of Certificate of Registration

PHARMA-Q (PTY) LTD

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2093, Johannesburg

South Africa

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To be confirmed

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31/3.1/0289

Access to the corresponding Professional Information

To be confirmed.