

## PACKAGE INFORMATION LEAFLET

### Proxyren Capsules

### Piroxicam USP 20mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet**

- a. What Proxyren Capsules is and what it is used for
- b. Before you take Proxyren Capsules
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#### **a. What Proxyren Capsules are and what they are used for**

Piroxicam is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This means it will help to relieve pain and reduce swelling affecting joints.

Piroxicam is used to relieve some symptoms caused by rheumatoid arthritis, osteoarthritis (joint disease) 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 Proxyren Capsules to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

#### **b. What you need to know before you take Proxyren Capsules**

Do not take Proxyren Capsules and tell your doctor if you:

- Are allergic to piroxicam or any of the other ingredients of this medicine (listed in Section f).
- Have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach.
- Have a history or stomach bleeding of perforation which may be related to the use of NSAIDs (naproxen, ibuprofen, diclofenac) or aspirin.
- Have a history of skin hypersensitive (allergic) reactions such as exfoliative dermatitis (reddening of skin), Stevens-Johnson syndrome (a rash, blistering and peeling of skin) or toxic epidermal necrolysis (blistering and peeling of the top layer of skin).
- Have a history of allergy to aspirin, ibuprofen or NSAIDs, which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose.

- Have a history of, or active 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).
- Have severe heart failure.
- Are taking other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac or acetylsalicylic acid (aspirin).
- Are taking anticoagulants, such as warfarin, to prevent blood clots.
- Are in the last three months of pregnancy.

If any of the above applies to you, tell your doctor immediately and do not take Proxyren Capsules.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of piroxicam, 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, 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 piroxicam, you must not be re-started on piroxicam at any time.

If you develop a rash or skin symptoms, you should stop taking Proxyren Capsules immediately, seek prompt medical advice and tell your doctor that you are taking this medicine.

### **Warnings and precautions**

Before prescribing Proxyren Capsules, your doctor will assess the benefits this medicine may give you against your risk of developing side effects. Your doctor may need to give you check-ups and will tell you how often you need to be checked during treatment with this medicine.

Talk to your doctor or pharmacist before taking Proxyren Capsules if you:

- Suffer from asthma
- Are elderly. Your doctor may prescribe another medicine to protect your stomach and intestines from side effects, particularly if you are over 70 years old or are taking other medication. You should not take this medicine if you are over 80 years of age.
- Suffer from liver or kidney disease.
- Have diabetes.
- High blood pressure, heart problems or stroke
- High cholesterol or hardening of the arteries
- Have unusual abdominal symptoms.

Proxyren Capsules may be associated with a small 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 heart problems, previous stroke or think you may be at risk of these conditions (for example if you have high blood pressure,

diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

### **Other medicines and Proxiren Capsules**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

The following medicines must not be taken with Proxiren Capsules:

- Aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief e.g. naproxen, diclofenac
- Anticoagulants such as warfarin to prevent blood clots.

Tell your doctor before you take Piroxicam if you are taking any of the following medicines:

- Corticosteroids, which are drugs given to treat a variety of conditions such as allergies and hormone imbalances
- Certain medicines used to treat heart conditions known as cardiac glycosides such as digoxin
- Certain medicines for depression such as lithium
- Selective serotonin re-uptake inhibitors (SSRIs) used to treat depression, as these can increase the risk of gastro-intestinal bleeding e.g. Fluoxetine, paroxetine, citalopram
- Antihypertensives to treat high blood pressure
- Methotrexate which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis
- Cyclosporin, which is given to help prevent rejection of transplanted organs can increase the risk of kidney problems when used with Piroxicam
- Quinolone antibiotics, which are used to treat various infections
- Mifepristone which is used to medically terminate pregnancies as NSAIDs can reduce the effects of mifepristone and so should not be used for 8-12 days after mifepristone
- Diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems (water tablets) can increase the risk of kidney problems when used with Piroxicam
- Anti-platelet agents (used to prevent blood clots from forming that can lead to heart attack or stroke) e.g. aspirin, clopidogrel, ticlopidine, dipyridamole
- Tacrolimus which is used to suppress the immune system after organ transplant can increase the risk of kidney problems when used with Piroxicam
- Cimetidine, used in the treatment of heartburn and peptic ulcers.

### **Taking Piroxicam with food and drink**

Proxiren Capsules should be taken with or after food.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take Piroxicam if you are in the last three months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take piroxicam during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, piroxicam can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. It is not usually recommended at other stages of pregnancy, but you may be able to take it if your doctor advises that it is necessary for you.

#### *Impaired female fertility*

The use of piroxicam may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, should talk to doctor and stop taking this medicine.

#### **Driving and using machines**

Proxyren Capsules may cause dizziness, drowsiness, fatigue or affect your vision. If affected, do not drive or operate machinery.

#### **Proxyren Capsules contains lactose**

Proxyren Capsules contain lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Proxyren Capsules.

#### **Proxyren Capsules contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

#### **c. How to take Proxyren Capsules**

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

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of piroxicam. Your doctor will adjust your treatment to the lowest dose. If continued treatment is considered necessary, this should be accompanied by frequent review.

Swallow your capsules whole with a glass of water. It is advisable to take your capsules at the same time each day with food or soon after eating.

#### **Adults:**

The maximum daily dose of Piroxicam is 20mg.

#### **Elderly:**

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

If you feel that the medicine is not very effective, always talk to your doctor. Do not increase the dose.

**If you take more Proxyren Capsules than you should**

If you accidentally take too many Proxyren Capsules, tell your doctor at once or go to the nearest casualty department. Always take the labelled medicine package with you, whether there is any Proxyren Capsules medicine left or not.

**If you forget to take Proxyren Capsules**

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 forgotten dose.

**If you stop taking Proxyren Capsules**

Continue to take the capsules for as long as your doctor tells you to. Talk to your doctor if you have any concerns.

**d. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking this medicine 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 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)
- yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems
- increased risk of heart attack (myocardial infarction)
- increased risk of stroke
- 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 section b).

**Common: may affect up to 1 in 10 people**

- Changes in the red blood cells which may result in unusual bruising or bleeding
- Changes in the white blood cells which may result in increased risk of infection
- Lowering of blood platelet count (thrombocytopenia)
- Anorexia
- Increase in blood sugar levels
- Dizziness
- Headache
- Vertigo (a spinning sensation)
- Sleepiness
- Ringing in ears (tinnitus)
- Abdominal pain/discomfort

- Constipation
- Diarrhoea
- Wind
- Feeling sick (nausea)
- Being sick (vomiting)
- Indigestion
- Itching
- Skin rash
- Swelling of the feet, hands or other parts of the body (oedema)
- Weight increased serum transaminase levels

**Uncommon: may affect up to 1 in 100 people**

- Blurred vision
- Fast or pounding heartbeat
- Sore mouth and/or lips
- Decreased/low blood sugar level

**Rare: may affect up to 1 in 1,000 people**

- Kidney inflammation
- Kidney failure
- Kidney damage
- Change in urine output or appearance

**Not known: frequency cannot be estimated from the available data**

- an allergic reaction to an injection of serum which can include fever, rash and joint pain.
- Abnormalities in the blood e.g. decreased haemoglobin
- Fluid retention
- Depression
- Dream abnormalities
- Hallucinations
- Changes in sleep patterns
- Mental confusion
- Mood alterations
- Nervousness
- Pins and needles
- Eye irritations
- Swollen eyes
- Hearing impairment
- High blood pressure
- Inflammation of the blood vessels
- Shortness of breath
- Constriction of the muscles lining the airways of lungs (bronchial)

- Nose bleeds
- Inflammation of the stomach lining (gastritis)
- Gastrointestinal bleeding including vomiting of blood and black, tarry stools
- Inflamed pancreas (which may lead to severe pain in the upper abdomen or back)
- Stomach (peptic) ulcers
- Hair loss
- Allergic reaction involving purple spots on the skin, joint pain, abdominal pain and kidney dysfunction (Henoch-Schoenlein purpura)
- Swelling of the lower layer of skin and tissue which can affect the eyes, lips, hands and feet
- Skin rashes including peeling skin, particularly around the mouth, nose, eyes and genitals (Erythema multiforme)
- Hives
- Itchy red rash, blisters which might be painful and filled with pus (Vesiculo bullous reactions)
- Skin allergic reactions such as exfoliative dermatitis (reddening of skin). See section b.
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching
- Loosening or splitting of fingernails
- Increased sensitivity of the skin to sunlight
- Decreased fertility in females
- Feeling unwell, general aches and pains
- Weight decrease
- Glomerulonephritis (group of diseases that injure the part of the kidney that filters blood (called glomeruli)).

Decreases in hemoglobin and hematocrit unassociated with obvious gastro-intestinal bleeding

- Aplastic anaemia (reduce in production of new blood cells).
- Severe stomach pain due to a hole in the stomach, large bowel or small intestine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **e. How to store Proxyren Capsules**

Do not store above 30°C. Protect from light.

Keep out of reach of children.

Do not use Proxyren Capsules 10 mg and 20 mg after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**f. Contents of the pack and other information**

**What Proxyren Capsules contain**

Each hard gelatin capsule contains Piroxicam USP 20mg

The other ingredients are:

Maize starch, Lactose, Microcrystalline cellulose, Magnesium stearate, Sodium lauryl sulphate

**What Proxyren Capsules look like and contents of the pack**

Maroon colored cap/ Maroon colored body '2' size capsules PROXYREN-20 imprinted on body, Rene Rene imprinted on cap with white ink, contains off white colored powder.

10 Capsules are packed in Aluminium/PVC blister; such 10 blisters are packed in a unit carton along with literature insert.

**MANUFACTURED BY**

RENE INDUSTRIES LIMITED

Plot 680, Kamuli, Kireka

P.O Box 6034, Kampala, Uganda



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