

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

Piroxicam 0.5%w/w Gel

(Piroxicam)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Piroxicam is and what it is used for
2. Before using Piroxicam
3. How to use Piroxicam
4. Possible side effects
5. How to store Piroxicam
6. Further information

1. What Piroxicam is and what it is used for

Piroxicam 0.5%w/w Gel (hereinafter referred to as Piroxicam) is a gel containing the active ingredient Piroxicam. Piroxicam helps to relieve inflammation, pain and stiffness.

Piroxicam belongs to a group of medicines called topical non-steroidal anti-inflammatory drugs (often shortened to NSAIDs) which are applied to the skin to reduce inflammation (swelling) and pain.

Piroxicam works by blocking the production of chemicals (prostaglandins) which the body produces in response to injury or certain diseases. These prostaglandins would otherwise go on to cause swelling and pain.

Piroxicam can be used to treat:

- muscle or joint pain caused by rheumatism or injury
- pain from arthritis (knee)
- pain or swelling from a sprain, back strain or bruise
- tennis elbow.

2. Before using Piroxicam

Do not use Piroxicam if you have or have had:

- an allergic (hypersensitive) reaction to piroxicam or any of the other ingredients of Piroxicam Gel (see section 6 for other ingredients).
- asthma that is made worse by aspirin or other painkilling medicines.
- an allergic reaction to aspirin or any other anti-inflammatory painkiller (for example if you had an itchy red rash, hay-fever like symptoms or asthma after taking these medicines).

Special warnings

Do not get this medicine in your eyes, nose or mouth. If the gel does accidentally go in your eyes or mouth wash it out immediately, then contact your doctor. If you accidentally swallow some of the gel, contact your doctor immediately.

Avoid contact with inflamed or broken skin. Do not put a plaster, bandage or another topical medicine on the area you have applied the gel to because it may affect the way the gel works.

The gel can sometimes make your skin more sensitive to sunlight and to prevent this happening you should try to keep the treated area out of the sun.

Speak to your doctor or pharmacist if you have:

- a history of serious allergic drug reactions, especially of the skin
- suffered a skin reaction before, however severe, to Piroxicam taken by mouth, to other anti-inflammatory medicines (NSAIDs) or to any other medicines
- liver problems
- kidney problems.

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 restarted on piroxicam at any time. If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell them that you are using this medicine.

Taking other medicines

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

You must tell your doctor or pharmacist if you are already taking any of the following medicines:

- aspirin
- other painkillers.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not use Piroxicam if you are pregnant, think you might be pregnant or are breast-feeding.

Driving and using machines

Piroxicam should not have an effect on your ability to drive or use machinery.

Important information about some of the ingredients of Piroxicam Gel

This gel contains propylene glycol, which can cause allergic reactions in some people. If you have been told by your doctor that you are allergic to propylene glycol contact your doctor before using this medicine.

3. How to use Piroxicam

Always use Piroxicam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

(continued overleaf)

Apply the gel three or four times a day as required.

There is a seal on the nozzle of this tube. Break this seal by pushing the pointed end of the cap onto the nozzle. If the seal is already broken when you buy the gel, return it to your pharmacist.

Wash your hands before using the gel. Also, wash your hands when you have finished using the gel unless your hands are the area being treated.

Squeeze about one and a quarter inches (3cm) of the gel onto your finger or hand and gently massage it onto the skin around the injury. If you have more than one injury, repeat on each area.

Do not use the gel for more than 4 weeks. Speak to your doctor if you still have symptoms after this time.

Piroxicam is not suitable for children under 12 years of age.

If you use more Piroxicam than you should:

Talk to your doctor or pharmacist.

Do not use more than 25g of the gel in one day (this would be about 25 applications).

Applying large amounts of Piroxicam may increase the chance of side effects.

If you forget to use Piroxicam

Apply as soon as you remember. If it is close to your next application miss the forgotten application and apply as normal. Do not double the amount to make up for a forgotten application.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

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

If you experience any of the following side effects **stop using the gel** and speak to your doctor **immediately**:

- breathlessness,
- rash, bruising or blistering of the skin
- potentially life-threatening skin rashes (Stevens Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely (see section 2).

Other side effects may include:

- skin becoming red, sore, itchy, painful, numb or tingly (contact dermatitis)
- itchy rash (scale-like) caused by sunlight.

Rarely, side effects include:

- feeling sick
- upset stomach.

These side effects should disappear when you stop using the gel.

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

5. How to store Piroxicam

Keep medicines out of the sight and reach of children. This product should not be used after the expiry date which appears at the end of the tube.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Piroxicam contains

This medicine contains piroxicam 0.5%w/w in a gel. It also contains propylene glycol, isopropyl alcohol, macrogol 7 glyceryl cocoate, hypromellose, sodium hydroxide, sodium metabisulphite, potassium dihydrogen phosphate and purified water.

What Piroxicam looks like and contents of the pack

The gel is available in 60g or 112g tubes.

Marketing Authorisation Holder:

Manx Healthcare Ltd., Taylor Group House, Wedgnoek Lane, Warwick, CV34 5YA, United Kingdom.

Distributed by

TEVA UK Ltd., Eastbourne, BN22 9AG.

Manufacturer:

C.P.M. ContractPharma GmbH & Co. KG
Frühlingstrasse 7, 83620 Feldkirchen, Westerham, Germany.

POM

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General information on treating and preventing muscular and soft tissue injuries

What can I do to help recover from injury?

Rest the area to prevent further tissue damage.

Ice may be used to reduce swelling (a bag of frozen peas makes a convenient ice pack). Place a wet towel on the skin and apply only for short, ten minute periods.

Compress injuries carefully with a bandage for support. (Wash off any Piroxicam 0.5%w/w Gel first).

Elevate the injury slightly above the rest of the body to reduce swelling.

Don't massage or apply heat to an acute injury within the first 48 hours.

Gently start to mobilise the injury as soon as possible without causing pain.

Return to normal activity gradually.

If symptoms are severe or persist, always see the advice of an experienced physiotherapist or your doctor.

How can I reduce the risk of injury?

Before you play sport or exercise, always warm up first (15 minutes minimum) and warm down gently afterwards (5 minutes minimum).

Don't attempt heavy or awkward movement at work or in the home.

Get assistance and use appropriate tools and equipment. Don't play sport competitively if you are tired or in pain.

Don't ignore the first signs of injury - stop the activity and rest.

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