

PIROXICAM 0.5% GEL

Piroxicam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Please keep this leaflet. You may need to read it again.
 - If you have any further questions, please ask your doctor or pharmacist.
 - This medicine has been prescribed for you only.

Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Piroxicam 0.5% Gel is and what it is used for
2. What you need to know before you use Piroxicam 0.5% Gel
3. How to use Piroxicam 0.5% Gel
4. Possible side effects
5. How to store Piroxicam 0.5% Gel
6. Content of the pack and other information

1. WHAT PIROXICAM 0.5% GEL IS AND WHAT IT IS USED FOR

The name of your medicine is Piroxicam 0.5% Gel. The active ingredient in this medicine is piroxicam. Piroxicam is one of a group of medicines called non-steroidal anti-inflammatory drugs. Piroxicam gel will help to relieve pain and reduce swelling affecting joints and muscles when rubbed into the skin over the affected area. It is used for the treatment of rheumatism (pain or inflammation in or around the bones, muscles or joints), sprains, strains and mild osteoarthritis of joints (knees, wrists, ankles etc).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PIROXICAM 0.5% GEL

Do not use this medicine if:

- You had an allergic reaction to aspirin or other anti-inflammatory medicines used to treat painful joints and muscles.
- You ever had an allergic reaction to Piroxicam or any of the other ingredients of this medicine (listed in section 6). (Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing).
- You are under 12 years of age.

Warnings and precautions

If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking or using.

Talk to your doctor before using Piroxicam Gel. Your doctor needs to know before you use Piroxicam Gel, if you suffer

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from or have suffered in the past from any of the following condition(s):

- Kidney disease
- 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 and genitals or 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 using piroxicam immediately, seek prompt medical advice and tell your doctor that you are using this medicine.

NSAIDs, including Piroxicam Gel, may cause kidney damage or kidney failure.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

Piroxicam Gel is not recommended for use in children under 12 years of age.

Other medicines and Piroxicam Gel

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

Pregnancy, breast-feeding and fertility

If you are trying to become pregnant or being investigated for infertility, withdrawal of Piroxicam Gel should be considered. Piroxicam Gel may increase the risk of miscarriage in early pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Piroxicam 0.5% Gel contains propylene glycol

This medicinal product contains 150mg propylene glycol per gram. Propylene glycol may cause skin irritation. Do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.

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3. HOW TO USE PIROXICAM 0.5% GEL

- Always use your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. He or she will tell you how your medicine should be used.
- To apply Piroxicam 0.5% Gel, pierce the tube by reversing the cap and screwing down to break the seal on the tube. Apply 3cm (1 1/4" approximately) of the gel onto the affected area.
- Rub the gel into the skin until the gel disappears. Do this three or four times a day. If the gel is not rubbed in completely, mild but temporary staining of the skin and staining of clothing may occur.
- For muscle sprains and strains you should start to feel better within one week. If the pain has not got any less after a week, tell your pharmacist or doctor.
- Do not use Piroxicam 0.5% Gel for more than four weeks without telling your pharmacist or doctor. Do not rub your medication into broken or damaged skin, for example wounds, scratches, infections or dermatitis.
- Do not apply near eyes, nose, mouth, genital or anal areas. If the gel does come into contact with these areas, rinse away with water.
- Avoid excessive exposure to sunlight of the area treated in order to prevent a possible allergic type reaction with light (photosensitivity).
- Do not cover the area where Piroxicam 0.5% Gel has been rubbed in with dressings or bandages.
- Piroxicam 0.5% Gel is for external use only.

After using Piroxicam 0.5% Gel

1. Always replace the cap.
2. Wash your hands, unless it is your hands that are being treated.

If you accidentally swallow Piroxicam 0.5% Gel

If a large amount of your medication is swallowed accidentally, tell your doctor immediately, or contact your nearest hospital casualty department.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause unwanted side effects in some people, although it is generally well tolerated. You are unlikely to get any of the following, but if you do, **tell your doctor immediately**:

- Redness and itching of the skin where the gel was rubbed in;
- Wheeziness, difficulty breathing or tightness in the chest;
- Swelling of the eyelids, face or lips;
- Life-threatening skin reactions (progressive skin rash often with blisters or mucosal lesions)
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching (frequency unknown).

These symptoms could be the signs of an allergic reaction or photosensitivity.

Other side effects may include:

- Nausea
- Indigestion
- Stomach discomfort

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These effects should disappear if you stop using Piroxicam 0.5% Gel. If the discomfort continues, tell your doctor or pharmacist.

If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist immediately**.

If you become unwell or have any discomfort that you do not understand while you are using Piroxicam 0.5% Gel, tell your doctor or pharmacist.

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 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.

5. HOW TO STORE PIROXICAM 0.5% GEL

Do not store above 25°C. Keep the tube tightly closed. Do not use after the expiry date that is stated on the carton. The expiry date refers to the last day of that month.

KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN

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.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Piroxicam 0.5% Gel contains

Each gram of Piroxicam 0.5% Gel contains 5 mg of piroxicam. The other ingredients are: propylene glycol, isopropyl alcohol, macrogol 7 glyceryl cocoate, hypromellose, sodium hydroxide, sodium metabisulphite, potassium dihydrogen phosphate and water.

What Piroxicam 0.5% Gel looks like and the contents of the pack

Aluminium tube with inner protective lacquer and polypropylene screw cap. A tube contains 60 g or 112 g of Piroxicam gel

Marketing Authorisation Holder:

Accord Healthcare Limited, Sage House, 319 Pinner Road North Harrow, Middlesex, HA1 4HF, United Kingdom

Manufacturer:

Tiofarma B.V., Benjamin Franklinstraat 5-10, 3261 LW Oud-Beijerland, The Netherlands.

This leaflet does not contain all the available information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. The information in this leaflet applies only to Piroxicam 0.5% Gel.

This leaflet was last approved in: January 2021