

PACKAGE LEAFLET: Information for the user

PainGo

Gel – 0.5%

(Piroxicam)

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

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

In this leaflet:

1. What PainGo is and what it is used for
2. What you need to know before you use PainGo
3. How to use PainGo
4. Possible side effects
5. How to store PainGo
6. Other information

1. WHAT PAINGO IS AND WHAT IT IS USED FOR

PainGo gel contains the active substance piroxicam which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It should be applied to the skin.

PainGo gel is indicated for the treatment of various painful and inflammatory conditions such as osteoarthritis, post-traumatic or acute musculoskeletal conditions such as tendonitis (inflammation of the tendon), tenosynovitis (inflammation of the outer sheath of the tendon), periarthritis (inflammation of the tissues surrounding a joint), sprains, strains and low back pain.

You should contact your doctor or pharmacist if you feel no improvement or if you feel less well.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PAINGO

Do not use PainGo:

- if you are allergic to piroxicam or any of the other ingredients of this medicine (listed in section 6). In addition, there is a possibility of cross-sensitivity (allergy to several substances at the same time) to acetylsalicylic acid (aspirin) and other nonsteroidal anti-inflammatory drugs;
- if acetylsalicylic acid (aspirin) and other nonsteroidal anti-inflammatory drugs (NSAIDs) cause symptoms of asthma, rhinitis, angioedema, or urticaria;
- on damaged skin.

Warnings and Precautions

Ask your doctor or pharmacist before using PainGo 0.5% gel.

Cases of life-threatening skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of piroxicam and cannot be excluded with PainGo. Initially, they appear as red circular spots (often with a blister in the center). Other signs to watch out for include painful ulcers in the mouth, throat, nose and genital area, and also conjunctivitis (red, swollen eyes). These potentially fatal rashes are often associated with flu-like symptoms (headache, fever and pain). The risk of serious skin reactions is highest in the first weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis while using piroxicam, you must never use PainGo gel again.

If you develop any rash or skin symptoms, you must stop using PainGo immediately, consult your doctor promptly, and inform them that you are using this medicine.

- If local irritation occurs, stop applying the gel.
- Do not apply to eyes, mucous membranes or open skin lesions. Do not apply in the presence of a skin condition on the surface to be treated.
- Do not use occlusive dressings.

- NSAIDs, including PainGo 0.5% gel, can cause kidney damage or failure.
- Treatment duration should not exceed 2 to 3 weeks.
- It is recommended to wash hands after application.
- PainGo 0.5% gel is not recommended for use in children under 12 years of age.

Other medicines and PainGo 0.5% gel

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without prescription.

Pregnancy and breastfeeding

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

NSAIDs, including PainGo 0.5% gel, can make it difficult to become pregnant. You should inform your doctor or pharmacist if you intend to become pregnant, or if you have trouble becoming one.

If you are breastfeeding, contact your doctor, who will decide whether to discontinue breastfeeding or discontinue PainGo.

Driving and using machines

PainGo is not expected to affect your ability to drive or use machines.

PainGo 0.5% gel contains propylene glycol and ethanol

This medicinal product contains 250 mg 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.

This medicinal product also contains 300 mg ethanol per gram. It may cause burning sensation on damaged skin.

3. HOW TO USE PAINGO

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

PainGo gel is for external use only. Do not use occlusive dressings. Rub the gel into the skin until no trace of the product remains.

Wash your hands after application.

The quantity of PainGo 0.5% gel to be used depends on the surface of the area to be treated. A maximum of 3 cm gel should be applied 3 to 4 times a day.

Use in children

In children, PainGo can be used from the age of 12.

Your doctor will tell you how long you should use PainGo gel. The duration of treatment should not exceed 2 to 3 weeks.

If you use more PainGo than you should

If you accidentally use too much PainGo Gel this is unlikely to cause any side effects.

If a large amount of your medication is swallowed accidentally, tell your doctor immediately.

If you forget to use PainGo

Do not use a double dose to make up for a missed application.

If you have any further questions about the use of this medicine, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Skin and subcutaneous tissue disorders

Mild to moderate local irritation, redness, rash, desquamation, itching and similar local reactions at the site of application, contact dermatitis, eczema and skin reaction to light.

Potentially fatal skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (very rare frequency).

Undetermined frequency: fixed erythema pigmentosum (which may resemble round or oval patches of redness and swelling of the skin), blisters (urticaria), itching.

Other side effects that PainGo gel may cause are:

Non-steroidal anti-inflammatory drugs in general can have adverse effects on the kidneys and gastrointestinal system.

These effects should disappear if you stop using PainGo gel. If the discomfort continues tell your doctor or pharmacist.

5. HOW TO STORE PAINGO

Keep this medicine out of the sight and reach of children!

Do not store above 25°C!

Do not use PainGo 0.5% after the expiry date which is stated on the package.

6. OTHER INFORMATION

What PainGo 0.5% gel contains

The active substance is piroxicam.

1 g gel contains 5 mg piroxicam.

The other ingredients are: carbomer, hydroxypropyl cellulose, ethanol, diethanolamine, propylene glycol, lavender oil, purified water.

Content of the pack

Carton box with an aluminium tube of 50 g

Marketing Authorization Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was formulated in January 2024.