

Package leaflet: Information for the patient

UNITED KINGDOM

Feldene® 0.5% w/w Gel 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 questions, 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Feldene Gel is and what it is used for

Feldene Gel 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 and muscles when rubbed into the skin over the affected area.

Feldene Gel is for the treatment of rheumatism, sprains, strains and mild osteoarthritis of joints (knees, wrists, ankles etc).

2. What you need to know before you use Feldene Gel

Do not use Feldene Gel

- If you are allergic to piroxicam or any of the other ingredients of this medicine (listed in section 6), any other form of piroxicam, aspirin or any other medicines used to treat painful joints and muscles. This may have been itching, reddening of the skin or difficulty in breathing.

Warnings and precautions

Talk to your doctor or pharmacist before taking Feldene Gel. Medicines are not always suitable for everyone. Your doctor needs to know before you use Feldene Gel if you suffer from or have suffered in the past from any of the following conditions:

- liver disease.
- kidney disease.

Potentially life-threatening skin rashes, including DRESS syndrome, Stevens-Johnson syndrome, and 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.

Treatment should be discontinued at the first appearance of skin rash, blistering and peeling of the skin, mucosal lesions, or any other sign of hypersensitivity. If you develop a rash or skin symptoms, you should stop taking Feldene Gel immediately, seek prompt medical advice and tell your doctor that you are taking this medicine. These reactions have not been associated with topical piroxicam, but the possibility of occurring with topical piroxicam cannot be ruled out. Reported cases of DRESS syndrome following piroxicam use have been present only after systemic treatment, and the likelihood of DRESS syndrome following topical treatment is currently unknown.

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

Children and adolescents

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

Other medicines and Feldene Gel

Feldene Gel is not known to interact with any other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

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

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.

Driving and using machines

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

Feldene Gel contains propylene glycol, benzyl alcohol and ethanol

Feldene Gel contains 200mg/g propylene glycol. Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

Feldene Gel contains 10mg/g benzyl alcohol. Benzyl alcohol may cause mild local irritation and may also cause allergic reactions.

Feldene Gel contains 240 mg/g alcohol (ethanol). The alcohol may cause a burning sensation on damaged skin.

The alcohol from this product may be absorbed through the skin in babies and may cause systemic toxicity. In babies less than 4 weeks old, including those babies that are prematurely born, high concentrations of ethanol may cause severe local reactions and also general toxic side effects as it would be absorbed through the baby's skin (especially if skin is covered).

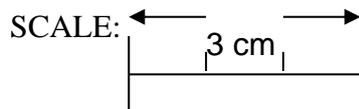
3. How to use Feldene Gel

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

Feldene Gel is for external use on the skin only.

Pierce the tube by reversing the cap and screwing down to break the seal on the tube.

Apply 3cm (1 ¼" approximately) of the Gel on the affected area. Use the scale below as a guide. Rub the Gel into the skin until the Gel disappears. Do this three or four times a day. If there is no improvement in your symptoms, tell your doctor. If the gel is not rubbed in completely, mild but temporary staining of the skin and staining of clothing may occur.



Do not use Feldene Gel for more than four weeks without telling your pharmacist or doctor.

Do not rub your medication into damaged skin, for example wounds, scratches, infections or dermatitis. Do not apply near eyes, nose, mouth, genital or anal (bottom) areas. If the Gel does come into contact with these areas, rinse away with water.

Do not cover the area where Feldene Gel has been rubbed in with dressings or bandages.

After using Feldene Gel

1. Always replace the cap
2. Wash your hands

If you use too much or accidentally swallow Feldene Gel

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

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

If you forget to use Feldene Gel

If you forget to use Feldene Gel, use it as soon as you remember unless it is time for your next application. Do not use double the amount to make up for a missed application.

If you stop using Feldene Gel

Your pain may return if you stop using Feldene Gel.

If you have any further questions on how to take this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately and stop using Feldene Gel if you experience any of the following symptoms after applying this medicine. Although they are very rare, these symptoms can be serious:

- sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching affecting the whole body
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely (see section 2).

Other side effects that Feldene Gel may cause are:

- Redness, rash and/or itching of the skin where Feldene Gel was rubbed in (for example eczema, contact dermatitis)
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching. The frequency of this reaction is unknown.
- Reaction of the skin to sunlight

Uncommon side effects are:

- Nausea (feeling sick)
- Indigestion
- Stomach discomfort

These effects should disappear if you stop using Feldene Gel. If the discomfort continues 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 Feldene Gel

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stamped on the tube and carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

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. Contents of the pack and other information

What Feldene Gel contains

The active substance is piroxicam. Each gram of Feldene Gel contains 5 mg piroxicam.

The other ingredients are benzyl alcohol (E1519), carbopol 980, di-isopropanolamine, ethanol, hydroxy-ethyl cellulose, propylene glycol (E1520) and purified water.

For benzyl alcohol, ethanol and propylene glycol see Section 2, “Feldene Gel contains propylene glycol, benzyl alcohol and ethanol”.

What Feldene Gel looks like and contents of the pack

Feldene Gel is clear, pale yellow and smells of alcohol. Each tube of Feldene Gel contains either 60 g or 112 g of gel. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Limited, Ramsgate Road,
Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer

Farmasierra Manufacturing S.L.,
Carretera de Irun, Km 26.200
E-28700 San Sebastian de los Reyes, Spain.

Company Contact Address

For further information on your medicine please contact Medical Information at the following address: Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone: 01304 616161.

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