

Package Leaflet: Information for the user

Feldene® 5mg/g 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
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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 in the last 3 months of pregnancy.
- if you have ever had an allergic reaction 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.
- on broken, damaged, infected or diseased skin.
- if you are under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using 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
- stomach ulcers or inflammatory bowel disorders (e.g. Crohn's 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.

Before prescribing Feldene Gel 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 Feldene Gel. This may be more frequent if you are elderly.

Whilst using Feldene Gel, it may take longer than usual for the bleeding to stop if you cut or injure yourself. You may also bruise more easily.

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

Other medicines and Feldene Gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking anticoagulants, e.g. warfarin, to prevent blood clots, or aspirin.

Pregnancy, breast-feeding and fertility

Feldene belongs to a group of medicines, NSAIDs, which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that Feldene, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before using this medicine if you have problems becoming pregnant or are trying to become pregnant.

Feldene may increase the risk of miscarriage in early pregnancy.

Oral forms (e.g., tablets) of piroxicam can cause adverse effects in your unborn baby. It is not known if the same risk applies to Feldene Gel.

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 you use this medicine. Do not use Feldene Gel if you are in the last 3 months of pregnancy. You should not use Feldene Gel during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

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).

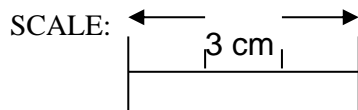
3. How to use Feldene Gel

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 (1¼" 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. If the Gel is not rubbed in completely, mild but temporary staining of the skin and staining of clothing may occur. Do this two to four times a day. 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.



Elderly patients should apply the smallest amount of gel which provides adequate relief.

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 use 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.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely (see section 2).

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

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 HPR

Pharmacovigilance. Website: www.hpra.ie. 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 stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original tube to protect from light.

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 5mg piroxicam.

The other ingredients are benzyl alcohol (E1519), carbomer 980, di-isopropanolamine, ethanol, hyetellose, 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 contains 30 g or 60g of Feldene Gel. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

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 contact Medical Information at the following address:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin
24, Ireland. Telephone 1800 633 363

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