



Package leaflet: Information for the patient

FELDENE[®] 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, pharmacist or nurse. 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

What Feldene Gel is

Feldene Gel is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

How Feldene Gel works

Feldene Gel will help to relieve pain and reduce swelling affecting joints and muscles when rubbed into the skin over the affected area.

What Feldene Gel is used for

Feldene Gel is used for the treatment of sprains, strains, low back pain and mild osteoarthritis of joints (knees, wrists, ankles etc) and also used for disorders of the muscles, nerves, tendons, joints.

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 cause 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.

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.

Cases of fixed skin reaction (fixed drug eruption - FDE) have been reported with piroxicam. Piroxicam should not be reintroduced in patients with history of piroxicam-related FDE. Potential cross reactivity might occur with other oxicams (see section 4 Possible side effects).

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.

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 and breast-feeding

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

If you are trying to become pregnant or being investigated for infertility, withdrawal of Feldene Gel should be considered. The safety of topical Feldene Gel use during pregnancy or during lactation has not known.

Driving and using machines

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

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.

A 1-gram dose of the 0.5% gel (corresponding to 5 mg of piroxicam) should be applied to the affected site three or four times per day.

Rub in the gel, leaving no residual material on the skin. 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.

1. After using Feldene Gel

1. Always replace the cap
2. Wash your hands

2. 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

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



Your pain may return if you stop using Feldene Gel.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of these effects may be serious.

Tell your doctor immediately and stop using Feldene Gel if you experience any of the following symptoms after applying this medicine. The majority of side effects involved mild or moderate **fixed skin reaction (fixed drug eruption)**, local irritation, redness, rash and/or itching of the skin at the application site. Additional skin reactions were also noticed like reaction of the skin to sunlight, reaction to irritants with an itchy, red rash, often with bumps and blisters, cracked skin.

Mild but transient skin discolouration and staining of clothing have been noted when the gel is not rubbed in completely.

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

5. How to store Feldene Gel

Store at controlled room temperature 20°C to 25°C (68°F to 77°F).

6. Contents of the pack and other information

What Feldene Gel contains

Hydroxyethyl cellulose
 Carbopol 940
 Purified water
 Benzyl Alcohol
 Propylene Glycol
 Isopropyl Alcohol
 Di-isopropanolamine

What Feldene Gel looks like and contents of the pack

Feldene Gel: Tube of 25 g

Feldene Gel/PIL/PK-02

According to Feldene Gel /LPD/PK-03/CDS V 9.0 dated: 02 September 2021

Marketed by:

Pfizer Pakistan Limited