

FELDENE Gel®

Piroxicam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FELDENE Gel.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using FELDENE Gel against the benefits they expect it will have for you.

If you have any concerns about using FELDENE Gel, ask your doctor or pharmacist.

Read this leaflet carefully before using FELDENE Gel and keep it with your medicine. You may need to read it again.

What FELDENE Gel is used for

FELDENE Gel is used to temporarily relieve the pain and inflammation associated with:

- Sprains/Strains
- Tendonitis.

FELDENE Gel belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Although it can relieve the symptoms of pain and inflammation (heat, throbbing, swelling, redness), it will not cure the underlying tissue damage and it will not treat bruises. Feldene Gel is not a heat rub.

Your doctor or pharmacist may recommend FELDENE Gel for other purposes.

Before you use FELDENE Gel

When you must not use it

1. Do not use FELDENE Gel if you have an allergy to:

- piroxicam (the active ingredient in FELDENE Gel) or any of the ingredients listed at the end of this leaflet
- other medicines containing piroxicam (Feldene, Feldene-D, Pirox, Mobilis, Candy, Fensaid)
- aspirin
- any other medicine that is a NSAID.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.

If you are not sure if you are taking one of these medicines, ask your doctor or pharmacist.

Signs of an allergic reaction to these medicines may include

- asthma, wheezing or shortness of breath
- runny nose
- nasal polyps (growths inside your nose)
- swelling of the face, lips, or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

If you are allergic to aspirin or NSAID medicines and use FELDENE Gel, these symptoms may be severe.

If you are not sure whether you should be using FELDENE Gel, talk to your doctor or pharmacist.

- 2. Do not use FELDENE Gel if the expiry date marked on the packaging has passed, even though the gel may look alright.**
- 3. Do not use FELDENE Gel if the packaging is torn or shows signs of tampering**
- 4. Do not let children of 12 years and under use FELDENE Gel.** There is not enough information to recommend the use of FELDENE Gel in children of this age group.
- 5. Do not use on broken or infected skin.**

Before you start to use it

You must tell your doctor or pharmacist if:

- 1. You are allergic to any other medicines, foods, dyes or preservatives.**
- 2. You have any of these medical conditions, or have had them in the past:**
 - stomach ulcers
 - bleeding from the bowel or stomach
 - asthma
 - kidney, liver or heart problems
 - raised blood pressure
 - swelling with fluid (oedema)
 - bleeding problems
 - inflammation of the intestines such as Crohn's disease.

3. **you are pregnant or breast feeding**

Like most NSAID medicines, FELDENE Gel is not recommended for use during pregnancy or breast feeding. NSAIDs have been associated with reversible infertility in some women. The use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion.

Your doctor or pharmacist will discuss the risks and benefits of using it.

Taking other medicines

Tell your doctor or pharmacist if you are taking ANY other medicines, including any medicine you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines important to mention include:

- aspirin and salicylates (e.g. Disprin, Aspro)
- other NSAID medicines (e.g. Voltaren, Naprosyn)
- warfarin, a medicine used to stop blood clots (e.g., Coumadin, Marevan)
- methotrexate, a medicine used to treat arthritis and some cancers
- phenytoin, a medicine used to treat epilepsy
- certain antibiotics called sulphonamides
- some medicines used to treat diabetes
- lithium, a medicine used to prevent or treat certain mental health disorders
- cimetidine, a medicine used to treat ulcers
- frusemide, also known as a "fluid" tablet, is a medicine used to remove excess fluid from the body.

If you are not sure if you are taking any of the medicines mentioned in this leaflet, check with your doctor or pharmacist.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using FELDENE Gel.

If you have not told your doctor or pharmacist about these things, tell them before you start using FELDENE Gel.

How to use FELDENE Gel

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information given in this leaflet.

How to apply the gel

Use the gel only on healthy skin. Do not put it on open wounds or injuries or on skin that has a rash or infection.

Rub in 1 g of the gel (approximately 3 cm or 1 and a quarter inches) to the sore or swollen area, 3 or 4 times a day.

It is important to rub the gel in completely, because any gel left on the skin may cause mild (but temporary) staining of the skin or clothes.

Wash your hands after each application.

Do not cover the affected area with a dressing or bandage

How long to use it

FELDENE Gel may be used for up to two weeks only.

If your symptoms do not improve after two weeks or get worse, stop using it and tell your doctor or pharmacist.

If you forget to use it

Use it as soon as you remember then go back to using it as you would normally.

Do not use twice as much to make up for what you have missed.

If you use too much (overdose)

If you, a child or anyone else, accidentally swallows FELDENE Gel, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If used properly on your skin, there is little risk of overdosage with this medicine.

While you are using FELDENE Gel

Things you must do

If you become pregnant while using FELDENE Gel, tell your doctor or pharmacist immediately.

Tell all doctors, dentists and pharmacists you visit that you are using FELDENE Gel.

If you are about to start any new medicines, tell your doctor or pharmacist that you are using FELDENE Gel.

Things you must not do

Do not let the gel get in your eyes. If this happens, rinse your eyes with clean water and tell your doctor or pharmacist.

Do not put it inside the mouth or vagina.

Never swallow the gel.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use FELDENE Gel to treat any other medical complaints unless your doctor or pharmacist says you can.

Side effects

Tell your doctor or pharmacist as soon as possible if you have any problems while using FELDENE Gel, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, FELDENE Gel may cause some side effects.

However, very little of the active ingredient passes into the blood stream; if side effects do occur, most are likely to be minor and temporary.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- mild itching, redness, swelling, blistering or dermatitis of the skin in the treated area.

Mild skin irritation may occur where the gel was applied.

Tell your doctor or pharmacist immediately if you notice any of the following:

- feeling sick (nausea)
- indigestion
- stomach pain.

If any of the following happen, STOP using Feldene Gel and tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips or tongue which may cause difficulty swallowing or breathing
- asthma, wheezing or shortness of breath
- sudden or severe itching, skin rash, or hives over larger areas of skin.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects have been reported very rarely when the active ingredient in FELDENE has been taken by mouth as tablets or capsules.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

After using FELDENE Gel

Storage

Keep FELDENE Gel where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep FELDENE Gel in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills

Heat and dampness can destroy some medicines.

Always replace the cap after use.

Disposal

If your doctor or pharmacist tells you to stop using FELDENE Gel, or the expiry date has passed, ask your pharmacist what to do with any leftover gel.

Product description

What it looks like

FELDENE Gel is a clear, pale yellow gel. It comes in tubes of 25 grams or 50 grams.

Ingredients

The active ingredient of FELDENE Gel is piroxicam. There are 5 mg of piroxicam in each gram of gel.

The inactive ingredients are:

- benzyl alcohol
- carbomer 980
- di-isopropanolamine
- ethanol
- hydroxyethylcellulose
- propylene glycol
- water.

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