

Package Leaflet: Information for the User
Feldene® 10 mg and 20 mg hard capsules
piroxicam

Read all of this leaflet carefully before you start taking 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 is and what it is used for
2. What you need to know before you take Feldene
3. How to take Feldene
4. Possible side effects
5. How to store Feldene
6. Contents of the pack and other information

1. What Feldene is and what it is used for

Feldene 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.

Feldene is used to relieve some symptoms caused by osteoarthritis (joint disease), rheumatoid arthritis, and ankylosing spondylitis (rheumatism of the spine) such as swelling, stiffness and joint pain. This medicine does not cure arthritis and will help you only as long as you continue to take it.

Your doctor will only prescribe Feldene to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take Feldene

Do not take Feldene

- If you previously had an allergic reaction to piroxicam, (the active ingredient in this medicine) or any of the other ingredients of this medicine (listed in section 6), other NSAIDs or any other medications, especially serious skin reactions (regardless of severity) such as erythema multiforme (patches of red, raised skin), Stevens-Johnson syndrome or toxic epidermal necrolysis (see below)
- If you have previously had or currently have a stomach or intestinal ulcer, bleeding or perforation
- If you have, or have previously had disorders of the stomach or intestines such as ulcerative colitis, Crohn's disease, gastrointestinal cancers or diverticulitis (inflamed or infected pouches/pockets in the colon)
- If you are taking other NSAIDs such as ibuprofen, celecoxib or acetylsalicylic acid (aspirin), a substance present in many medicines used to relieve pain and lower fever
- If you are taking non-aspirin NSAIDs such as COX-2 inhibitors

- If you are taking anticoagulants, such as warfarin/coumarin-type and novel oral anticoagulants (e.g. apixaban, dabigatran, rivaroxaban),, to prevent blood clots
- If you are allergic (hypersensitive) to peanut or soya
- If you have heart failure.

If any of the above applies to you, **tell your doctor immediately and do not take Feldene.**

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, 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.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Warnings and precautions

Talk to you doctor, pharmacist or nurse before using Feldene. Before prescribing Feldene (piroxicam), 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.

Medicines such as Feldene may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment or if you are a smoker. Do not exceed the recommended dose or duration of treatment.

Feldene can cause potentially life-threatening hepatitis and jaundice. Although rare if clinical signs consistent with liver disease develop, seek immediate advice from a doctor.

Talk to your doctor or pharmacist before you take Feldene if you suffer from or have suffered in the past from any of the following conditions:

- liver disease
- kidney disease
- high blood pressure, heart problems or stroke
- high cholesterol or hardening of the arteries
- diabetes
- bleeding in the brain or any other blood clotting disorder
- problems with metabolism (patients who are known or suspected to be poor metabolisers of CYP2C9 substrates, such as warfarin or phenytoin)

If you have or had any other medical problems or any allergies or if you are not sure as to whether you can use Feldene tell your doctor before taking this medicine.

You should **stop taking Feldene immediately** and **tell your doctor** if you have any allergic reaction such as a skin rash, swelling of the face, wheezing or difficulty breathing.

Take special care with Feldene as like all NSAIDs, Feldene can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration and perforation. Use of Feldene for a short or long duration can increase the risk of these serious reactions in the stomach and intestines, and the risk is also increased with doses greater than 20 mg per day. The risk of serious reactions in the stomach and intestines may be higher with Feldene than with other NSAIDs.

You should **stop taking Feldene immediately** and **tell your doctor** if you have severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements or vomiting blood.

Your doctor may prescribe Feldene together with another medicine to protect your stomach and intestines from side effects, particularly if you are over 70 years old, or you are taking other medicines like corticosteroids (medicines given to treat a variety of conditions such as allergies and hormone imbalances), certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or low dose acetylsalicylic acid (aspirin) to help prevent heart attacks or stroke.

Piroxicam may make it more difficult to become pregnant. Tell your doctor if you are trying for a baby or having tests for infertility, as piroxicam may not be suitable for you.

If you experience problems with your eyesight while taking Feldene tell your doctor as you may need to have your eyes checked.

Patients over 70 years of age

If you are over 70 years old, your doctor may wish to minimise the length of your treatment and to see you more often while you are taking Feldene.

You should not take this medicine if you are over 80 years of age.

Other medicines and Feldene

Tell your doctor or pharmacist if you are taking, have recently taken (in the last week) or might take any other medicines. Medicines can sometimes interfere with each other. Your doctor may limit your use of Feldene or other medicines, or you may need to take a different medicine.

The following medicines **must not be taken with Feldene**:

- aspirin or other non-steroidal anti-inflammatory medicines for pain relief
- anticoagulants such as warfarin to prevent blood clots

Tell your doctor or pharmacist **before** you take Feldene if you are taking any of the following medicines:

- corticosteroids, which are medicines given to treat a variety of conditions such as allergies and hormone imbalances
- low dose aspirin (75 mg) to help prevent heart attack or stroke
- digoxin or digitoxin, which are used to treat heart conditions
- certain medicines for depression such as lithium or selective serotonin re-uptake inhibitors (SSRIs)
- antihypertensives including angiotensin-converting enzyme (ACE) inhibitors, angiotensin II antagonists (AIIA) and beta blockers to treat high blood pressure
- methotrexate, which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis

- medicines given to help prevent rejection of transplant organs, such as ciclosporin and tacrolimus
- aminoglycoside antibiotics, such as streptomycin, which are used to treat serious infections
- probenecid, a medicine used to treat gout
- diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems
- medicines for diabetes that are taken by mouth, such as chlorpropamide.

Feldene with food, drink and alcohol

Feldene should be taken with food or meals. Alcohol should be avoided when being treated with Feldene since alcohol can increase the risk of serious gastrointestinal side effects such as stomach ulcers and bleeds.

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.

Use of piroxicam in pregnancy is not recommended. Feldene may increase the risk of miscarriage in early pregnancy. If used during the second or third trimester of pregnancy, it might cause a reduction of amniotic fluid volume through its potential effect on foetal kidneys. If Feldene is prescribed, the pregnant woman should be closely monitored. It can also cause premature closure of a foetal blood vessel in the heart which can be serious. It is recommended that Feldene is avoided during the third trimester of pregnancy.

Feldene is not recommended for use if you are breast-feeding, as clinical safety has not been established.

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

These capsules can cause some people to feel dizzy, drowsy, tired or have problems with their vision. If you are affected, do **not** drive or operate machinery.

Feldene contains lactose

Feldene contains 243.23 mg or 233.23 mg lactose, a type of sugar, in Feldene 10 mg and 20 mg capsules, respectively. If you have been told that you have an intolerance to some sugars, contact your doctor before taking Feldene.

Feldene contains soya lecithin. If you are allergic to soya or peanut do not use this medicinal product.

3. How to take Feldene

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

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of Feldene. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms. Under no circumstances should you change your dose without first speaking to your doctor.

Swallow your capsules **whole** with a glass of water. It is best to take your capsules at the same time each day with food or soon after eating.

The recommended dose is:

Adults:

The maximum daily dose of Feldene is 20 milligrams taken as one single daily dose.

Elderly:

If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment.

If you feel that the medicine is not very effective, always talk to your doctor. Do not increase the dose.

If you take more Feldene than you should

If you accidentally take too much Feldene contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Feldene left or not.

If you forget to take Feldene

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a forgotten dose.**

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

4. Possible side effects

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

Tell your doctor immediately and stop taking Feldene if you experience any of the following symptoms after taking this medicine:

- any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements or vomiting blood
- sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe skin reactions including a rash with blisters (vesiculo-bullous reactions) and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or extensive peeling of the skin (toxic epidermal necrolysis)
- yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems

Common: may affect up to 1 in 10 people

- Changes in the red blood cells which may result in unusual bruising or bleeding
- Changes in the white blood cells which may result in increased risk of infection
- A reduced appetite (anorexia)
- Increase in blood sugar levels
- Dizziness
- Headache
- Vertigo (a spinning sensation)
- Drowsiness
- Ringing in ears (tinnitus)
- Abdominal pain/discomfort
- Constipation
- Diarrhoea
- Wind
- Feeling sick (nausea)

- Being sick (vomiting)
- Indigestion
- Itching
- Skin rash
- Swelling of the feet, hands or other parts of the body (oedema)
- Weight increase
- Changes in other biochemical tests including those for kidney and liver function (e.g. increased serum transaminase and blood urea nitrogen (BUN))

Uncommon: may affect up to 1 in 100 people

- Blurred vision
- Fast or pounding heartbeat
- Sore mouth and/or lips
- Decreased/low blood sugar
- Increased blood levels of creatinine (a break-down product of muscles removed by the kidneys)

Very rare: may affect up to 1 in 10,000 people

- Potentially life-threatening skin rashes including peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or extensive peeling of the skin (toxic epidermal necrolysis) (see section 2)

Not known: frequency cannot be estimated from the available data

- Abnormalities in the blood e.g. decreased haemoglobin, hematocrit, positive antinuclear body (ANA)
- Fluid retention
- Sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- Depression
- Dream abnormalities
- Hallucinations
- Changes in sleep patterns
- Mental confusion
- Mood alterations
- Nervousness
- Pins and needles
- Eye irritations
- Swollen eyes
- Hearing impairment
- High blood pressure
- Inflammation of the blood vessels
- Shortness of breath
- Constriction of the muscles lining the airways of lungs (bronchial)
- Nose bleeds
- Inflammation of the stomach lining (gastritis)
- Gastrointestinal bleeding including vomiting of blood and black, tarry stools
- Inflamed pancreas (which may lead to severe pain in the upper abdomen or back)
- Stomach (peptic) ulcers
- Upset stomach
- Worsening of the symptoms associated with colitis or Crohn's disease
- Inflammation of the mouth or mouth ulcers
- Hair loss
- Rapid swelling of the eyes, lips, hands, genitals and feet
- Allergic reaction involving purple spots on the skin, joint pain, abdominal pain and kidney dysfunction (Henoch-Schoenlein purpura)
- Rashes, blistering, peeling, itching, redness, tenderness, thickening or scaling of skin
- Loosening or splitting of fingernails

- Increased sensitivity of the skin to sunlight
- Decreased fertility
- Feeling unwell, general aches and pains
- Weight decrease
- Yellowing of the skin and the whites of your eyes (jaundice)
- Inflammation of the liver (hepatitis)
- Increased risk of heart attack (myocardial infarction)
- Increased risk of stroke
- Kidney inflammation
- Kidney failure
- Kidney damage
- Change in urine output or appearance
- Kidney pain or pain in abdomen

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Feldene

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 carton and the bottle label. 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 contains

The active substance is piroxicam. Feldene comes in two strengths; 10 mg or 20 mg. Each 10 mg capsule contains 10 mg of piroxicam and each 20 mg capsule contains 20 mg piroxicam.

The other ingredients are: lactose monohydrate, maize starch, vegetable magnesium stearate and sodium laurel sulfate.

The 10 mg capsule shells contain gelatin, red iron oxide (E172), indigotin (E132) and titanium dioxide (E171). The 20 mg capsule shells contain gelatin and titanium dioxide (E171). The printing ink contains shellac (E904), black iron oxide (E172) and soya lecithin (E322).

What Feldene looks like and contents of the pack

Feldene 10 mg capsules are blue and red marked FEL 10 and Pfizer.
Feldene 20 mg capsules are white marked FEL 20 and Pfizer.

Feldene 10 mg capsules come in containers of 30.
Feldene 20 mg capsules come in containers of 30.

Marketing Authorisation Holder

Pfizer Limited, Ramsgate Road, Sandwich,
Kent, CT13 9NJ, UK.

Manufacturer

Fareva Amboise, Zone industrielle – 29 route des Industries,
37530-Pocé-sur-Cisse, France.

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.

This leaflet was last revised in MM/YYYY.

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Ref: FE 24_1