

Package leaflet: Information for the patient
Feldene® Melt 20 mg
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. 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 Melt is and what it is used for
2. What you need to know before you take Feldene Melt
3. How to take Feldene Melt
4. Possible side effects
5. How to store Feldene Melt
6. Contents of the pack and other information

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

Feldene Melt 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.

Feldene Melt 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 Melt to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take Feldene Melt

Do not take Feldene Melt

- 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 anticoagulants, such as warfarin, to prevent blood clots.
- 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 exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), Stevens-Johnson syndrome (symptoms are a rash, blistering or peeling of the skin, mouth, eyes or genitals) or toxic epidermal necrolysis (a disease with blistering and peeling of the top layer of skin).

- If you have severe heart failure.
- If you are in the last three months of pregnancy.

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

Warnings and precautions

Potentially life-threatening skin rashes (DRESS syndrome, 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 skin symptoms, you should stop taking Feldene Melt immediately, seek prompt medical advice and tell your doctor that you are taking this medicine.

Take special care with Feldene Melt

Before prescribing Feldene Melt (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 Melt.

Medicines such as Feldene Melt 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.

Tell your doctor before you take Feldene Melt 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
- asthma
- diabetes
- phenylketonuria (PKU) which is a genetic disorder.

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 Melt tell your doctor before taking this medicine.

You should **stop taking Feldene Melt 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 Melt as like all NSAIDs, Feldene Melt can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration and perforation.

You should **stop taking Feldene Melt immediately** and **tell your doctor** if you have 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 Melt 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 attack or stroke.

Feldene Melt may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

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 Melt.

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

Other medicines and Feldene Melt

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

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

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

Tell your doctor **before** you take Feldene Melt 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 (75mg) to help prevent heart attack or stroke
- certain medicines used to treat heart conditions known as cardiac glycosides, such as digoxin
- certain medicines for depression such as lithium or selective serotonin re-uptake inhibitors (SSRIs)
- antihypertensives to treat high blood pressure
- methotrexate, which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis
- ciclosporin or tacrolimus, which are given to help prevent rejection of transplanted organs
- quinolone antibiotics e.g. ciprofloxacin, which are used to treat various infections
- mifepristone, a medicine used to terminate pregnancy
- diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems.

Feldene Melt with food and drink

Feldene Melt should be taken with or after food.

Pregnancy, breast-feeding and fertility

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. Do **not** take Feldene Melt if you are in the last three months of pregnancy. It is not usually recommended at other stages of pregnancy, but you may be able to take it if your doctor advises that it is necessary for you.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

These tablets 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 Melt contains aspartame

Feldene Melt contains 0.25 mg aspartame in each tablet. Aspartame is a source of phenylalanine. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Feldene Melt

Always take Feldene Melt exactly as your doctor 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 Melt. 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.

Adults:

The maximum daily dose of Feldene Melt 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.

How to remove the tablets

Your tablets are in a new type of packaging. Do **not** try to push the tablets through the foil as this will break the tablet. Instead follow the instructions.

- Hold the packet of tablets with the flat, printed side facing you.
- Peel back the loose flap at the edge of the packet to reveal a tablet.
- Tip the tablet into the palm of your hand.
- Place the tablet on your tongue and close your mouth.

The tablet will dissolve within a few seconds. If you prefer, you can swallow the tablet with some water.

If you take more Feldene Melt than you should

If you accidentally take too much Feldene Melt 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 Melt left or not.

If you forget to take Feldene Melt

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 the use of this product, 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 taking Feldene Melt 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)
- a rash, blistering or peeling of the skin, mouth, eyes or genitals
- 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
- Anorexia
- Increase in blood sugar levels
- Headache
- Dizziness
- Drowsiness
- Vertigo (a spinning sensation)
- Ringing in ears (tinnitus)
- Abdominal pain/discomfort
- Feeling sick (nausea)
- Constipation
- Wind
- Diarrhoea
- Being sick (vomiting)
- Indigestion
- Skin rash
- Itching
- Swelling of the feet, hands or other parts of the body (oedema)
- Abnormalities in the blood e.g. decreased haemoglobin
- Weight increase

Uncommon: may affect up to 1 in 100 people

- Blurred vision
- Fast or pounding heartbeat
- Sore mouth and/or lips
- Decreased/low blood sugar level

Rare: may affect up to 1 in 1,000 people

- Kidney failure
- Kidney damage
- Kidney inflammation
- Change in urine output or appearance
- Kidney pain or pain in abdomen

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

- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness

- Fluid retention
- Sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- Depression
- Hallucinations
- Mental confusion
- Mood alterations
- Changes in sleep patterns
- Nervousness
- Dream abnormalities
- Pins and needles
- Eye irritations
- Swollen eyes
- Hearing impairment
- Increased risk of heart attack (myocardial infarction)
- Increased risk of stroke
- Inflammation of the blood vessels
- High blood pressure
- Constriction of the muscles lining the airways of lungs (bronchial)
- Shortness of breath
- Nose bleeds
- Upset stomach
- Stomach (peptic) ulcers
- Inflamed pancreas (which may lead to severe pain in the upper abdomen or back)
- Gastrointestinal bleeding including vomiting of blood and black, tarry stools
- Inflammation of the stomach lining (gastritis)
- Inflammation of the liver (hepatitis)
- Yellowing of the skin and the whites of your eyes (jaundice)
- Serious allergic reaction which causes swelling of the face or the throat (angioedema)
- Rashes, blistering, peeling, itching, redness, tenderness, thickening or scaling of skin
- Increased sensitivity of the skin to sunlight
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching
- Allergic reaction involving purple spots on the skin, joint pain, abdominal pain and kidney dysfunction (Henoch-Schoenlein purpura)
- Loosening or splitting of fingernails
- Hair loss
- Decreased fertility
- Feeling unwell, general aches and pains
- Weight decrease

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 Melt

Keep all medicines out of the reach and sight of children.

Store below 25°C.

Do not use Feldene Melt after the expiry date which is stamped on the carton and the blister foil. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Feldene Melt contains

The active substance in Feldene Melt is piroxicam 20 mg.

Other ingredients are aspartame (E951) (see section 2 “Feldene Melt contains aspartame”), citric acid anhydrous, gelatin and mannitol.

What Feldene Melt looks like and contents of the pack

Feldene Melt tablets are white to off-white and are supplied in a pack containing 30 tablets.

Marketing Authorisation Holder

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

Manufacturer

Haupt Pharma Latina S.r.l.
Latina (LT)
Strada Statale 156 Km 47,600
04100 Borgo San Michele
Italy

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