

Feldene®; Feldene-D®

Piroxicam (pir-oks-i-kam)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FELDENE. 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 has weighed the risks of you taking FELDENE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What FELDENE is used for

FELDENE treats the symptoms of

- rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine.

Although FELDENE can relieve the symptoms of pain and inflammation, it will not cure your condition.

FELDENE belongs to a group of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation (heat, throbbing, swelling, redness).

Your doctor may have prescribed FELDENE for another reason.

Ask your doctor if you have any questions about why FELDENE has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take FELDENE

When you must not take it

Do not take FELDENE if you have an allergy to:

- piroxicam (the active ingredient in FELDENE) or any of the capsule or tablet ingredients listed at the end of this leaflet (see Product Description)
- other medicines containing piroxicam e.g. PIRIFEL, FELDENE Gel. Other brands are available.
- any medicine that is a COX-2 inhibitor
- aspirin
- any other medicine that is also an 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 pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- nasal polyps (growths inside the 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, NSAID or COX-2 inhibitor medicines and take FELDENE, these symptoms may be severe.

Do not take FELDENE if:

- **you are pregnant, or intend on becoming pregnant, unless your doctor says otherwise.**

Like most NSAID medicines, FELDENE is not recommended for use during pregnancy. It may affect your developing baby if you take it while you are pregnant, especially during the last three months of pregnancy.

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 will discuss the risks and benefits of taking FELDENE during pregnancy.

Pregnant woman taking FELDENE should be closely monitored by their doctor.

- **you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before**
- **you are vomiting blood, or material that looks like coffee grounds, or if this has happened to you recently**
- **you are bleeding from the rectum (back passage), have black sticky bowel motions (stools), or bloody diarrhoea, or if this has happened to you recently**
- **you have, or have had, inflammation of the lining of the stomach or bowel**
Some examples of these conditions include Crohn's disease and ulcerative colitis.
- **if you have severe liver disease**
- **if you have severe kidney disease.**

If you are not sure whether you should be taking FELDENE, contact your doctor.

Do not take FELDENE if the packaging is torn or shows signs of tampering.

Do not take FELDENE if the expiry date (EXP) printed on the pack has passed.

Do not give FELDENE to children of 12 years and under.

The safety and effectiveness of FELDENE in this age group have not been established.

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to:**
 - any other medicines including aspirin or other NSAID medicines
 - any other substances, such as foods, preservatives or dyes.
2. **you are breast-feeding or plan to breast-feed**
Like most NSAID medicines, the active ingredient in FELDENE passes into breast milk and may affect your baby. Your doctor will discuss the benefits and risks of taking FELDENE while breast-feeding.
3. **you have or have had any medical conditions, especially the following:**

- heartburn, indigestion, stomach ulcers or other stomach problems
- bowel or intestinal problems
- asthma
- kidney disease
- liver disease
- heart failure
- heart disease, Use of FELDENE may increase your risk of developing a heart condition such as heart attack even if you don't have a history of heart disease.
- high blood pressure
- swelling of the ankles or feet (oedema)
- a tendency to bleed.

4. **you currently have an infection**

If you take FELDENE while you have an infection, it may hide some of the signs of an infection (e.g. pain, fever, swelling or redness). This may make you think, mistakenly, that you are better or that it is not serious.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take FELDENE.

Taking other medicines

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

Some medicines and FELDENE may interfere with each other. These include:

- aspirin (including low doses used to prevent your blood from clotting in certain heart conditions), salicylates or other NSAIDs
- warfarin or similar medicines including Eliquis, Xarelto or Pradaxa that are used to stop blood clots
- digoxin or digitoxin, medicines used to treat heart failure
- tablets used to treat diabetes
- certain antibiotics called sulphonamides
- phenytoin, a medicine used to treat epilepsy
- lithium, a medicine used to treat some types of depression
- selective serotonin reuptake inhibitors, medicines used to treat depression
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- methotrexate, a medicine used to treat arthritis and some cancers
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- cholestyramine, a medicine used to reduce cholesterol.
- alcohol

These medicines may be affected by FELDENE or may affect how well it works. Your doctor or pharmacist has more information on medicines to be careful of or avoid while taking FELDENE.

How to take FELDENE

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

- the usual dose is between 10 mg and 20 mg, taken as a single dose each day.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose.

How to take it

Swallow the capsules whole with water.

If you are taking the dispersible tablets (FELDENE-D), allow the tablet to dissolve in a glass of water and then drink it straight away.

Try to take your FELDENE at the same time each day, either morning or evening.

It is best to take FELDENE immediately after food to avoid the chance of an upset stomach.

How long to take it

Keep taking FELDENE every day until your doctor tells you to stop.

You may need to take FELDENE for a long time.

If you need to take FELDENE for a long time, see your doctor for regular check-ups so that he/she can monitor your condition and treatment.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

If you are not sure what to do, check with your doctor or pharmacist.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much FELDENE. Do this even if there are no signs of discomfort or poisoning.

If you take too much FELDENE, you may feel sick or have stomach pain, vomiting, headache, dizziness, drowsiness and confusion.

While you are taking it

Things you must do

If you become pregnant while taking FELDENE, tell your doctor immediately.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking FELDENE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking FELDENE.

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking FELDENE.

FELDENE can slow down blood clotting.

If you get an infection while taking FELDENE, tell your doctor.

FELDENE may hide some of the signs of an infection (e.g. pain, fever, redness, swelling). You may think, mistakenly, that you are better or that the infection is not serious.

Things you must not do

Do not give FELDENE to anyone else, even if they have the same condition as you.

Do not take FELDENE to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how FELDENE affects you.

As with other NSAID medicines, FELDENE may cause dizziness, drowsiness or blurred vision in some people.

If this happens, do not drive or do things that could be dangerous if you are not alert.

Be careful of ingesting alcohol whilst taking FELDENE. As with other NSAIDs medicines ingesting alcohol may increase your risk of developing stomach problems. Side effects

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

Like other medicines, FELDENE can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Report any side effects promptly to your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

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

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- dizziness, light-headedness
- drowsiness, sleepiness
- headache
- buzzing or ringing in the ears
- sore mouth or tongue
- hair loss or thinning
- loose nails
- change in mood, for example depression.

These side effects are usually mild.

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

- severe pain or tenderness in the stomach
- visual disturbances such as blurred vision

- severe dizziness, spinning sensation
- fast or irregular heartbeat, also called palpitations
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purple blotches under the skin
- signs of anaemia such as tiredness, being short of breath and looking pale
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.

These are rare but serious side effects. You may need urgent medical attention.

If any of the following happen, STOP taking FELDENE and tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- vomiting blood or material that looks like coffee grounds
- bleeding from your back passage (rectum), black sticky motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may make swallowing or breathing difficult
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting
- pain or tightness in the chest.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

After taking FELDENE

Storage

Keep your capsules or tablets in their pack until it is time to take them.

If you take them out of their packaging, they will not keep well.

Keep them in a cool, dry place where the temperature stays below 30 °C. Do not store them, or any other medicine in the bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your capsules or tablets where young children cannot reach them.

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

Disposal

If your doctor tells you to stop taking FELDENE, or the capsules or tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

FELDENE capsules are available as:

- FELDENE 10 mg - blue/maroon, marked FEL10 on one side and Pfizer on the other.

A box contains 50 capsules.

- FELDENE 20 mg - maroon, marked FEL20 on one side and Pfizer on the other.

A box contains 25 capsules.

FELDENE-D dispersible tablets are available as:

- FELDENE-D 20 mg - white, scored, capsule-shaped, marked FEL/20 on one side and plain on the other.

A box contains 25 tablets.

Ingredients

FELDENE capsules contain either 10 mg or 20 mg piroxicam as the active ingredient.

FELDENE capsules also contain:

- lactose monohydrate
- maize starch
- magnesium stearate
- sodium lauryl sulfate
- gelatin
- erythrosine
- titanium dioxide
- brilliant blue FCF (133) (10 mg only)
- indigo carmine (120) (20 mg only).

FELDENE-D dispersible tablets contain 20 mg piroxicam as the active ingredient.

FELDENE-D dispersible tablets also contain:

- lactose monohydrate
- cellulose
- hydroxypropyl cellulose
- sodium stearyl fumarate.

FELDENE does not contain gluten or sugar.

Manufacturer

FELDENE is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free Number 1800 675 229

Australian Registration Number:

FELDENE 10 mg capsules - AUST R 47656

FELDENE 20 mg capsules - AUST R 47654

FELDENE-D 20 mg - AUST R 37312.

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