

FELDENE®; FELDENE-D®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FELDENE?

FELDENE contains the active ingredient piroxicam. FELDENE is used to treat the symptoms of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine.

For more information, see Section [1. Why am I using FELDENE?](#) in the full CMI.

2. What should I know before I use FELDENE?

Do not use if you have ever had an allergic reaction to FELDENE, if you have any active inflammatory disease or ulcers, if you have any kidney, liver or heart problems, any other medicine containing piroxicam, aspirin or medicines known as NSAIDs or any of the ingredients listed at the end of the CMI.

Do not take FELDENE if you are pregnant in your third trimester of pregnancy, or you are breastfeeding. If you are pregnant at any stage, please speak to your doctor first about this medicine.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use FELDENE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FELDENE and affect how it works. Examples of such medicines include aspirin or other NSAIDs, warfarin, digoxin, medicine for diabetes or epilepsy or depression, certain antibiotics, diuretics, medicine for blood pressure or cholesterol and alcohol. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FELDENE?

The usual dose of FELDENE 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.

More instructions can be found in Section [4. How do I use FELDENE?](#) in the full CMI.

5. What should I know while using FELDENE?

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| Things you should do | <ul style="list-style-type: none">● If you become pregnant while taking FELDENE, tell your doctor immediately.● If you get an infection while taking FELDENE, tell your doctor.● Tell all doctors, dentists and pharmacists who are treating you that you are taking FELDENE. |
| Things you should not do | <ul style="list-style-type: none">● 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. |
| Driving or using machines | <ul style="list-style-type: none">● Be careful driving or operating machinery until you know how FELDENE affects you.● As with other NSAID medicines, FELDENE may cause dizziness, |

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| | drowsiness or blurred vision. |
| Drinking alcohol | <ul style="list-style-type: none"> • Alcohol may interfere with FELDENE and may affect how well it works. Ask your doctor or pharmacist for more information. |
| Looking after your medicine | <ul style="list-style-type: none"> • Keep them in a cool, dry place where the temperature stays below 30°C. • Keep your capsules or tablets where young children cannot reach them. |

For more information, see Section [5. What should I know while using FELDENE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some of the common side effects are upset stomach (nausea or vomiting, cramps), diarrhoea or constipation, dizziness or lightheaded-ness, headache. Some side effects may be serious and need medical attention. If you experience serious allergic reaction, vomiting blood or see blood in stool, fainting or chest tightness/pain, go to Emergency at your nearest hospital immediately. If you are over

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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FELDENE®; FELDENE-D®

Active ingredient(s): *Piroxicam* (pir-oks-i-kam)

Consumer Medicine Information (CMI)

This leaflet provides important information about using FELDENE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FELDENE.**

Where to find information in this leaflet:

- [1. Why am I using FELDENE?](#)
- [2. What should I know before I use FELDENE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FELDENE?](#)
- [5. What should I know while using FELDENE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FELDENE?

FELDENE contains the active ingredient piroxicam. 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).

FELDENE is used to treat the symptoms of rheumatoid arthritis, osteoarthritis and 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.

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.

2. What should I know before I use FELDENE?

Warnings

Do not use FELDENE if:

1. You are allergic or hypersensitive 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), or other medicines containing piroxicam.
- 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.

2. You are taking aspirin or any other medicine that is also an NSAID
3. You have had a severe allergic reaction to any medicine in the past, especially skin reactions
4. You have had a skin reaction to piroxicam in the past
5. You have a gastric ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had gastric ulcers before
6. You have or have had inflammation and/or ulceration of the lining of the stomach or bowel

Some examples of these conditions include Crohn's disease and ulcerative colitis

7. You have severe kidney disease
8. You have severe heart failure
9. You have severe liver failure
10. You are about to have or have had recent coronary artery bypass surgery
11. You are in your third trimester of pregnancy or are breastfeeding

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.

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.

Tell your doctor if:

- You have any allergies to:
 - Any other medicines including aspirin or other NSAID medicines
 - Any other substances, such as foods, preservatives or dyes
- If you have or have had any of the following medical conditions
 - 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
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take FELDENE if you are pregnant, or intend on becoming pregnant, unless your doctor says otherwise.

FELDENE is not to be used at all during the third trimester of pregnancy.

FELDENE should not be used during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the baby. Seek advice from your doctor.

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.

Tell your doctor if you are breast-feeding or plan to breast-feed.

FELDENE is not to be used during breastfeeding.

Like most NSAID medicines, the active ingredient in FELDENE passes into breast milk and may affect your baby.

3. What if I am taking other medicines?

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

Some medicines may interfere with FELDENE and affect how it works. 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
- Colestyramine, a medicine used to reduce cholesterol
- Alcohol

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FELDENE.

4. How do I use FELDENE?

How much to take

- The usual dose is between 10 mg and 20 mg, taken as a single dose each day
- Follow the instructions provided and use FELDENE until your doctor tells you to stop

When and how long to take FELDENE

- 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
- 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.

How to take FELDENE

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.

If you forget to use FELDENE

FELDENE should be used regularly at the same time each day.

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

Do not take a double dose to make up for the dose you missed.

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

If you use too much FELDENE

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

You should immediately:

- Phone the Poisons Information Centre (**by calling 13 11 26**), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using FELDENE?

Things you should 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep your capsules or tablets in their pack until it is time to take them.
- Keep them in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine

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.

6. Are there any 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.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age, you may have an increased chance of getting side effects. Ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

| Common side effects | What to do |
|--|--|
| <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Stomach upset including nausea (feeling sick), vomiting• heartburn, indigestion, cramps• Loss of appetite• Constipation• Diarrhoea• Pain in the stomach• Wind <p>Alertness and sleep:</p> <ul style="list-style-type: none">• Dizziness• Light-headedness• Drowsiness, sleepiness <p>Aches and pains:</p> <ul style="list-style-type: none">• Headache• Sore mouth or tongue <p>Other</p> <ul style="list-style-type: none">• Buzzing or ringing in the ears• Hair loss or thinning• Loose nails | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> |

| Common side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> • Change in mood, for example depression | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Call your doctor immediately:</p> <p>Gastrointestinal symptoms:</p> <ul style="list-style-type: none"> • Severe pain or tenderness in the stomach <p>Skin related symptoms:</p> <ul style="list-style-type: none"> • Bleeding or bruising more easily than normal, reddish or purple blotches under the skin • Yellowing of the skin and eyes, also called jaundice • Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|-------------------|
| <p>Other:</p> <ul style="list-style-type: none"> ● Visual disturbances such as blurred vision ● Severe dizziness, spinning sensation ● Increase in blood pressure ● 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 ● Signs of anaemia such as tiredness, being short of breath and looking pale ● Unusual weight gain, swelling of ankles or legs <p>Seek Emergency medical attention:</p> | |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● 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 | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What FELDENE contains

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| Active ingredient (main ingredient) | Piroxicam (10 mg or 20 mg) |
| Other ingredients (inactive ingredients) | FELDENE capsules also contain: <ul style="list-style-type: none">• Lactose monohydrate• Maize starch• Magnesium stearate• Sodium lauryl sulfate• Gelatin• Erythrosine• Titanium dioxide• Brilliant blue FCF (133) (10 mg only) FELDENE-D dispersible tablets also contain: |

| | |
|----------------------------|--|
| | <ul style="list-style-type: none"> • Lactose monohydrate • Cellulose • Hydroxypropyl cellulose • Sodium stearyl fumarate |
| Potential Allergens | Feldene contains sugars (as lactose) |

Do not take this medicine if you are allergic to any of these ingredients.

What FELDENE looks like

FELDENE capsules are available as:

- FELDENE 10 mg - blue/red, marked FEL10 on one side and Pfizer on the other (Aust R 47656).

FELDENE-D dispersible tablets are available as:

- FELDENE-D 20 mg - white, oblong, scored, capsule-shaped, marked FEL/20 on one side and plain on the other (Aust R 37312).

Who distributes FELDENE

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in December 2022.

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