

# Fenac

contains the active ingredient diclofenac sodium

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet answers some common questions about Fenac.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Fenac against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

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### What Fenac is used for

Fenac is used to treat the symptoms of:

- \* different types of arthritis including rheumatoid arthritis and osteoarthritis
- \* other painful conditions where swelling is a problem, such as back pain, rheumatism, muscle strains, sprains and tendonitis (e.g. tennis elbow)
- \* menstrual cramps (period pain).

Fenac belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation (swelling and redness).

Although Fenac can relieve the symptoms of pain and inflammation,

it will not cure your condition.

Your doctor may have prescribed Fenac for another reason. Ask your doctor if you have any questions about why Fenac has been prescribed for you.

Fenac is not recommended for use in children as its safety and effectiveness in children has not been established.

There is no evidence that Fenac is addictive.

Fenac is available only with a doctor's prescription.

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### Before you take Fenac

#### **When you must not take it**

**Do not take Fenac if you are allergic to:**

- \* medicines containing diclofenac or any other NSAID medicine
- \* aspirin
- \* any of the ingredients listed at the end of this leaflet.

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 any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- \* asthma, wheezing or shortness of breath
- \* swelling of the face, lips or tongue, difficulty in swallowing or breathing

- \* hives, itching or skin rash
- \* fainting.

If you are allergic to aspirin or NSAID medicines and take Fenac, these symptoms may be severe.

**Do not take Fenac if you have any of the following medical conditions:**

- \* an ulcer (gastric or duodenal)
- \* bleeding from the stomach or bowel
- \* severe kidney or liver problems
- \* severe heart failure.

**Do not take this medicine during the last three months of pregnancy.**

It may affect your baby and may delay labour and birth.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

#### **Before you start to take it**

**Tell your doctor if you are allergic to:**

- \* any other medicines including aspirin or other NSAID medicines
- \* any other substances such as foods, dyes or preservatives.

**Tell your doctor if you are pregnant or plan to become pregnant.**

There is not enough information to recommend the use of Fenac during the first 6 months of pregnancy and it must not be used during the last 3 months. Fenac may also reduce fertility and affect your chances of

becoming pregnant. Your doctor can discuss the risks and benefits involved.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

Fenac passes into breast milk. Therefore, there is a possibility that the breastfed baby may be affected. Your doctor will discuss the risks and benefits of taking Fenac when breastfeeding.

**Tell your doctor if you have, or have had, any of the following medical conditions:**

- \* asthma or any other chronic lung disease that causes difficulty in breathing
- \* seasonal allergies (e.g. hay fever)
- \* polyps in the nose
- \* repeated chest infections
- \* kidney or liver problems
- \* heart problems
- \* a history of high blood pressure
- \* a history of peptic ulcers (ulcer of the stomach or duodenum) or severe attacks of indigestion or other stomach trouble
- \* vomiting blood or bleeding from your back passage
- \* diseases of the bowel such as Crohn's disease or ulcerative colitis
- \* a tendency to bleed or other blood problems such as anaemia
- \* recent major surgery.

**Tell your doctor if you currently have an infection.**

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

**If you have not told your doctor about any of the above, tell them before you start taking Fenac.**

## ***Taking other medicines***

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

Some medicines may be affected by Fenac or may affect how well Fenac works. These include:

- \* aspirin, salicylates or other NSAID medicines
- \* warfarin, a medicine used to prevent blood clots
- \* digoxin, a medicine used to treat heart failure and other heart conditions
- \* diuretics, also called fluid or water tablets
- \* medicines used to treat high blood pressure or heart conditions, including ACE inhibitors or beta-blockers
- \* medicines used to treat diabetes
- \* lithium, a medicine used to treat mood swings
- \* certain medicines used to treat depression called selective serotonin-reuptake inhibitors (SSRIs)
- \* methotrexate, a medicine used to treat arthritis and some types of cancer
- \* cyclosporin, a medicine used to help prevent organ transplant rejection or treat certain problems with the immune system
- \* corticosteroid medicines such as prednisone and cortisone
- \* certain antibiotics called quinolones

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Fenac.

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## **How to take Fenac**

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### ***How much to take***

The dose varies from patient to patient.

The usual dose starting dose to treat arthritis or other painful conditions where swelling is present is 75 to 150 mg a day. For long term treatment, your doctor may lower the dose depending on how you respond.

Elderly patients may need smaller doses.

For period pain, the dose starts at 50 to 100 mg a day and may be increased if necessary to a maximum of 200 mg a day.

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

### ***How to take it***

**Swallow the tablets whole with a glass of water.**

**Do not crush or chew the tablets.**

Fenac tablets have a special coating which helps to prevent stomach irritation. If you crush or chew the tablets, you will destroy the coating and increase the likelihood of a stomach upset.

### ***When to take it***

**Take Fenac with or after food.**

This may help reduce the possibility of stomach upset.

Fenac tablets are usually taken in 2 or 3 doses during the day.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

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

**If you are not sure what to do, ask your doctor or pharmacist.**

### ***How long to take it for***

**Take Fenac only for as long as your doctor recommends.**

For arthritis, Fenac usually begins to work within a few hours, but it may take several weeks before you feel the full effects of the medicine.

Fenac will not cure your condition but it should help control the pain, swelling and stiffness.

For period pain, Fenac is usually taken during each period as soon as the pain begins and continued for a few days until the pain goes away.

### ***If you take too much (overdose)***

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

You may need urgent medical attention.

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## **While you are taking Fenac**

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### ***Things you must do***

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

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Fenac.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Fenac.**

**If you are going to have surgery, including dental surgery, tell your**

**doctor or dentist that you are taking Fenac.**

NSAIDs can cause prolonged bleeding.

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

Fenac may hide some of the signs of an infection (such as pain, fever, redness, swelling). You may mistakenly think that you are better or that your infection is not serious.

**Visit your doctor regularly so that they can check on your progress.**

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

**If, for any reason, you have not taken Fenac exactly as prescribed, tell your doctor.**

Your condition may not improve or you may have unwanted side effects if you do not take the tablets as prescribed. Also, your doctor may think that Fenac is not working for you and change your treatment unnecessarily.

### ***Things you must not do***

**Do not use Fenac to treat any other conditions unless your doctor tells you to.**

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

**Do not take any other medicines to treat inflammation while you are taking Fenac without first checking with your doctor or pharmacist. These include:**

- \* aspirin
- \* other NSAIDs including gels, creams and some period pain medications.

If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, check with your doctor or pharmacist.

**Do not stop any other forms of treatment that your doctor has advised.**

This medicine does not replace exercise or rest programs or the use of heat/cold treatments.

### ***Things to be careful of***

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

Fenac may cause dizziness, drowsiness or blurred vision in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Fenac.**

Like all other medicines, Fenac may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

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

- \* stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- \* constipation, diarrhoea, wind
- \* loss of appetite
- \* dizziness, lightheadedness
- \* headache
- \* drowsiness, sleepiness
- \* difficulty sleeping, nightmares
- \* confusion, disorientation
- \* change in mood such as feeling depressed, anxious or irritable

- \* buzzing or ringing in the ears.

The first few side effects listed above are the more common reactions that may occur.

**Tell your doctor as soon as possible if you notice any of the following:**

- \* severe pain or tenderness in the stomach
- \* signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- \* bleeding or bruising more easily than normal, reddish or purple blotches under the skin
- \* tiredness, being short of breath, looking pale
- \* a change in the colour of urine passed, blood in the urine
- \* a change in the amount or frequency of urine passed, burning feeling when passing urine
- \* yellowing of the skin and eyes, itching of the skin, tiredness and lack of energy
- \* unusual weight gain, swelling of the ankles or legs
- \* symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- \* eye problems such as blurred or double vision
- \* severe or persistent headache
- \* tingling or numbness of the hands or feet
- \* fast or irregular heart beat, also called palpitations
- \* difficulty hearing.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, stop taking Fenac and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:**

- \* vomiting blood or material that looks like coffee grounds
- \* bleeding from the back passage (rectum), black sticky stools or bloody diarrhoea

- \* symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- \* signs of a serious skin reaction such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell
- \* fainting or convulsions (fits)
- \* pain or tightness in the chest.

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

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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

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## After using Fenac

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### Storage

**Keep Fenac where 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 your tablets in a cool dry place where the temperature stays below 25 degrees C.**

**Do not store Fenac or any other medicine in the bathroom or near a sink.**

**Do not leave Fenac in the car or on window sills.**

Heat and dampness can destroy some medicines.

## Disposal

**If your doctor tells you to stop taking Fenac, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

Fenac is available in two different strengths.

- \* Fenac 25 is a round brown enteric-coated tablet; each bottle contains 100 tablets
- \* Fenac 50 is a round brown enteric-coated tablet; each bottle contains 50 tablets.

### Ingredients

The active ingredient in Fenac is diclofenac sodium. Each Fenac 25 tablet contains 25 mg of diclofenac sodium and each Fenac 50 tablet contains 50 mg of diclofenac sodium.

The tablets also contain:

- \* lactose
- \* calcium hydrogen phosphate
- \* microcrystalline cellulose
- \* maize starch
- \* sodium starch glycollate
- \* magnesium stearate
- \* colloidal anhydrous silica
- \* methacrylic acid copolymer
- \* triethyl citrate
- \* talc
- \* titanium dioxide
- \* iron oxide yellow CI 77492

The tablets are gluten free.

### Supplier

Fenac is supplied by:  
 Alphapharm Pty Limited  
 (ABN 93 002 359 739)  
 Chase Building 2  
 Wentworth Park Road  
 Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

[www.alphapharm.com.au](http://www.alphapharm.com.au)

Australian registration numbers:

Fenac 25 – Aust R 145815

Fenac 50 - Aust R 145816

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