

FENAC[®] EC

diclofenac sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about FENAC EC.

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 EC 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.

What FENAC EC is used for

FENAC EC belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness).

FENAC EC is used to treat:

- 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)
- relieve pain in children after they have had an operation.

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

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

Your doctor may have prescribed it for another purpose.

FENAC EC is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend the use of FENAC EC tablets in children.

Before you take FENAC EC

When you must not take it

Do not take FENAC EC if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in FENAC EC) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- aspirin
- ibuprofen
- any other NSAID

If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema)
- rash, itching or hives on the skin.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or

NSAID medicines.

If you are allergic to aspirin or NSAID medicines and you use FENAC EC, these symptoms may be severe.

Do not take FENAC EC if you have had any of the following medical conditions:

- a stomach or intestinal ulcer
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- kidney or liver problems
- severe heart failure
- heart bypass surgery

Do not take FENAC EC during the first 6 months of pregnancy, except on doctor's advice. Do not take this medicine during the last three months of pregnancy.

Use of this medicine during the last 3 months of pregnancy may affect your baby and may delay labour and birth.

Use of non-aspirin NSAIDs can increase the risk of miscarriage, particularly when taken close to the time of conception.

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 have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies, especially if you get skin reactions with redness, itching or rash.

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

- established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease, or atherosclerotic cardiovascular disease) as treatment with FENAC EC is generally not recommended
- established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe FENAC EC, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- current or past history of gastrointestinal problems such as stomach or intestinal ulceration, bleeding or black stools, and/or stomach discomfort or heartburn after taking anti-inflammatory medicines in the past

- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis)
- past history of haemorrhoids (piles) or irritation of the rectum (back passage)
- liver or kidney problems
- a rare liver condition called porphyria
- bleeding disorders or other blood disorders (e.g. anaemia)
- asthma or any other chronic lung disease that causes difficulty in breathing
- hay fever (seasonal allergic rhinitis)
- repeated chest infections
- polyps in the nose
- diabetes
- dehydration (e.g. by sickness, diarrhoea, before or after recent major surgery)
- swollen feet

Your doctor may want to take special precautions if you have any of the above conditions.

It is generally important to take the lowest dose of FENAC EC that relieves your pain and/or swelling and for the shortest

time possible in order to keep your risk for cardiovascular side effects as small as possible.

Tell your doctor if you are pregnant or trying to become pregnant.

There is not enough information to recommend the use of FENAC EC during the first 6 months of pregnancy and it must not be used during the last 3 months. FENAC EC 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 currently have an infection.

If you take FENAC EC while you have an infection, some of the signs of the infection such as pain, fever, swelling and redness may be hidden. You may think, mistakenly, that you are better or that the infection is not serious.

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

Breast feeding is not recommended while taking FENAC EC. The active ingredient, diclofenac, passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking FENAC EC when breastfeeding.

Tell your doctor if you are lactose intolerant.

FENAC EC tablets contain lactose.

Tell your doctor if you are planning to give this medicine to a child.

Safety and effectiveness in children have not been established.

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

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 and FENAC EC may interfere with each other. These include:

- other anti-inflammatory medicines e.g. aspirin, salicylates or ibuprofen
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)
- digoxin (a medicine for heart problems)
- lithium or selective serotonin- reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure, heart conditions, glaucoma and migraine)

- prednisone, cortisone, or other corticosteroids (medicines used to provide relief for inflamed areas of the body)
- medicines (such as metformin) used to treat diabetes, except insulin
- methotrexate (a medicine used to treat arthritis and some cancers)
- ciclosporin, tacrolimus (a medicine used in patients who have received organ transplants)
- trimethoprim (a medicine used to prevent or treat urinary tract infections)
- some medicines used to treat infection (quinolone antibacterials)
- glucocorticoid medicines, used to treat arthritis
- sulfinpyrazone (a medicine used to treat gout)
- voriconazole (a medicine used to treat fungal infections)
- phenytoin (a medicine used to treat seizures)
- rifampicin (an antibiotic medicine used to treat bacterial infections)

You may need to take different amounts of your medicines or to take different medicines while you are using FENAC EC. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start using this medicine.

How to take FENAC EC

When to take it

It is recommended to take the tablets before meals or on an empty stomach. If they upset your stomach, you can take them with food or immediately after food.

They will work more quickly if you take them on an empty stomach but they will still work if you have to take them with food to prevent stomach upset.

How much to take

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

These instructions may differ from the information contained in this leaflet.

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

There are different ways to take FENAC EC tablets depending on your condition. Your doctor will tell you exactly how many tablets to take.

Do not exceed the recommended dose.

To treat arthritis or other painful conditions

The usual starting dose of FENAC EC tablets is 75 mg to 150 mg each day. After the early stages of treatment, it is usually possible to reduce the dose to 75 mg to 100 mg each day.

To treat menstrual cramps (period pain)

The tablets are usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.

The usual starting dose of FENAC EC tablets is 50 mg to 100mg each day, beginning as soon as cramps begin and continuing until the pain goes away, but for no longer than 3 days.

If necessary, the dose can be raised over several menstrual periods to a maximum of 200 mg each day.

How to take it

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

Swallow the tablets whole with a full glass of water or other liquid. Do not chew them.

The tablets have a special coating to keep them from dissolving until they have passed through the stomach into the bowel. Chewing the tablets would destroy the coating.

How long to take it for

Do not use FENAC EC for longer than your doctor says.

If you are using FENAC EC for arthritis, it will not cure your disease but it should help to control pain and inflammation. It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine.

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 your next dose when you are meant to.

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

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

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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 EC. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include vomiting, bleeding from the stomach or bowel, diarrhoea, dizziness, ringing in the ears or convulsions (fits).

While you are taking FENAC EC

Things you must do

If you take FENAC EC for more than a few weeks, you should make sure to visit your doctor for regular check-ups to ensure that you are not suffering from unnoticed undesirable effects.

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

Your doctor can discuss with you the risks of taking FENAC EC while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will periodically re-evaluate whether you should continue treatment with FENAC EC, if you have established heart disease or significant risks for heart disease, especially in case you are treated for more than 4 weeks.

Your doctor may want to check your kidneys, liver and blood from time to time to help prevent unwanted side effects.

If, at any time while taking FENAC EC you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately. These may be signs of cardiovascular toxicity.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking FENAC EC.

NSAID medicines can slow down blood clotting and affect kidney function.

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

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FENAC EC.

Tell any other doctors, dentists and pharmacists who treat you that you are taking FENAC EC.

Things you must not do

Do not take any of the following medicines while you are taking FENAC EC without first checking with your doctor or pharmacist:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other medicines containing diclofenac
- ibuprofen
- any other NSAID medicines.

If you take these medicines together with FENAC EC, they may cause unwanted side effects.

If you need to take something for headache or fever, it is recommended that you take paracetamol. If you are not sure, your doctor or pharmacist can advise you.

Do not stop any other forms of treatment for arthritis that your doctor has told you to follow.

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

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how FENAC EC affects you.

This medicine may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If any of these occur, do not drive, use machine or do anything else that could be dangerous.

Elderly patients should take the minimum number of tablets that provides relief of symptoms.

Elderly patients, especially those with a low body weight, may be more sensitive to the effects of FENAC EC than other adults.

Side effects

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

All medicines can have side effects. 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 should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

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, indigestion, cramps, loss of appetite, wind
- heartburn or pain behind or below the breastbone (possible symptoms of an ulcer in the tube that carries food from the throat to the stomach)
- stomach or abdominal pain
- constipation, diarrhoea
- sore mouth or tongue
- altered taste sensation
- headache
- dizziness, spinning sensation
- drowsiness, disorientation, forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods

- shakiness, sleeplessness, nightmares
- tingling or numbness of the hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of arms, hands, feet, ankles or legs due to fluid build-up
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth, and/or skin) that happen more quickly than normal
- skin inflammation with flaking or peeling
- vision disorders *(e.g. blurred or double vision)
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using this medicine after gastrointestinal surgery.

***If symptoms of vision disorders occur during treatment with FENAC EC, contact your doctor as an eye examination may be considered to exclude other causes.**

If any of the following signs appear, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- red or purple skin (possible signs of blood vessel inflammation)
- severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (possible stomach problems)
- rash, skin rash with blisters, itching or hives on the skin; swelling of the face, lips, mouth, tongue, throat, or other part of the body which may cause difficulty to swallow, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)
- wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma)
- yellowing of the skin and/or eyes (signs of hepatitis/liver failure)
- persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems)
- constant "flu-like" symptoms including chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy, bleeding or bruising more easily than normal (possible blood problem)
- painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals, which may be accompanied by fever and chills, aching muscles

and feeling generally unwell (possible serious skin reaction)

- signs of a possible effect on the brain, such as sudden and severe headache, stiff neck (signs of viral meningitis), severe nausea, dizziness, numbness, difficulty in speaking, paralysis (signs of cerebral attack), convulsions (fits)
- change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood or excess of protein in the urine (possible kidney disorders)
- sudden and oppressive chest pain (which may be a sign of myocardial infarction or a heart attack)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- Coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome)

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

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking FENAC EC

Storage

Keep your medicine in the original container until it is time to take it.

If you take the tablets out of the pack they may not keep well.

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

Do not store FENAC EC or any other medicine in the bathroom or near a sink.

Do not leave FENAC EC in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep FENAC EC 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.

Disposal

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

Product description

What it looks like

FENAC EC 25 mg tablets are round, pale yellow, enteric coated tablets plain on both sides. Available in blister packs of 50 tablets.

FENAC EC 50 mg tablets are round, pale brown, enteric coated tablets plain on both sides. Available in blister packs of 50 tablets.

Ingredients

FENAC EC contains 25 mg or 50 mg of diclofenac sodium as the active ingredient.

The tablets also contain the following inactive ingredients:

- colloidal anhydrous silica
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- maize starch
- povidone
- hypromellose
- iron oxide yellow
- iron oxide red (50 mg tablet only)
- titanium dioxide
- sodium starch glycollate type A
- purified talc

- PEG-40 hydrogenated castor oil
- methacrylic acid - ethyl acrylate copolymer (1:1)
- triethyl citrate

The tablets also contain sugars as lactose.

Supplier

FENAC EC is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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Australian registration numbers:

AUST R 272882 - FENAC EC diclofenac sodium 25 mg
enteric coated tablet blister pack

AUST R 272871 - FENAC EC diclofenac sodium 50 mg
enteric coated tablet blister pack

FENAC[®] is a Viatris company trade mark

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