

APO-Diclofenac

Enteric Coated Tablets

Diclofenac sodium

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Diclofenac is used to treat the symptoms of:

- rheumatoid arthritis
- osteoarthritis
- pain with swelling (back pain, muscle damage and tendonitis)
- painful periods (dysmenorrhoea)

Diclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It also has analgesic (painkilling) and antipyretic (fever reducing) properties.

Diclofenac acts by reducing pain (at rest and on movement), morning stiffness and swelling of the joints associated with rheumatic diseases, as well as improving function.

In addition, it has been shown to relieve period pain (dysmenorrhoea).

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

Your doctor may have prescribed diclofenac for another reason.

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

There is no evidence that this medicine is addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- diclofenac
- aspirin or any other NSAIDs
- any of the ingredients listed at the end of this leaflet
- lactose, or are lactose intolerant – these tablets contain a small amount of lactose

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have any of the following medical conditions:

- asthma or allergic-type reactions, where NSAIDs cause your symptoms to worsen
- stomach or duodenal ulcers
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- severe heart failure
- liver or kidney problems
- heart bypass surgery

Do not take this medicine during the first 6 months of pregnancy, except on a doctor's advice. Do not use during the last 3 months (last trimester) of pregnancy.

Diclofenac may affect your developing baby and may delay labour and birth if you take it at this stage of your pregnancy.

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

Do not breastfeed if you are taking this medicine.

Diclofenac passes into breast milk and there is a possibility that your baby may be affected.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- problems with your heart, such as heart failure or ischemic heart disease
- high blood pressure
- high cholesterol or high levels of fats in your blood
- diabetes
- a history of ulcers (stomach or intestinal)
- diseases of the stomach, bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative or ischemic colitis)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past
- liver or kidney problems

- asthma, hayfever/rhinitis, nasal polyps, lung disease or other breathing problems
- repeated chest infections
- serious skin conditions, such as exfoliative dermatitis, toxic epidermal necrolysis and Stevens-Johnson Syndrome
- problems with blood clotting or other blood disorders e.g. anaemia
- dehydration e.g. by sickness or diarrhoea, before or after recent major surgery
- a rare liver condition called porphyria
- problems with fluid retention such as swollen feet
- intolerance or allergy to lactose

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

Diclofenac may impair fertility in women. Your doctor can discuss with you the risks and benefits involved.

This medicine passes into breast milk. It is not recommended that you take this medicine whilst breastfeeding.

Tell your doctor if you currently have an infection.

Diclofenac can cover up some of the symptoms of infections, such as pain, fever, swelling or redness. You may think, mistakenly, that you are better or that the infection is not serious.

Tell your doctor if you are about to have or have just had an operation.

Diclofenac can slow down blood clotting and may affect kidney function and the healing process.

Tell your doctor if you smoke or drink large amounts of alcohol.

This can increase the chances of you having stomach problems or ulcers whilst taking this medicine.

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

Taking other medicines

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

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

- aspirin or any other anti-inflammatory (NSAID or COX-2 inhibitor) medications
- lithium or selective-serotonin reuptake inhibitors (SSRIs), medicines used to treat some types of depression
- digoxin, used for heart problems

- some medicines used to treat infections (quinolones antibiotics, trimethoprim or rifampicin)
- anticoagulants (e.g. warfarin) and other medicines for thinning the blood
- medicines (e.g. metformin) used to treat diabetes, except insulin
- methotrexate, used to treat rheumatoid arthritis and some cancers
- cyclosporin and tacrolimus, medicines used after organ transplants
- prednisolone, cortisone, other corticosteroids or glucocorticoids – used to provide relief for inflamed areas of the body
- medicines for blood pressure and heart problems (e.g. beta-blockers or ACE inhibitors)
- diuretics, also called fluid or water tablets
- voriconazole, used to treat serious fungal infections
- sulfinpyrazone, used to treat gout
- phenytoin, used to treat seizures

These medicines may be affected by diclofenac or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Note especially that the combination of diclofenac, ACE inhibitors and certain diuretics may seriously damage your kidneys.

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

How to take this medicine

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

They may be different to the information contained in this leaflet.

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

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether you are taking any other medicines.

The usual starting dose of diclofenac 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.

For period pain, the usual starting dose is 50 mg to 100 mg. If necessary, the daily dose can be increased over several months to a maximum of 200 mg/day.

Treatment should be started when the period pain starts, and stopped after it goes away.

How to take it

The daily dose should be divided into two or three doses taken during the day.

The tablets should be swallowed whole with a full glass of water or other liquid. These tablets should be taken with a meal.

Do not break, crush or chew the tablets.

When to take it

It is preferable to take this medicine with meals, but it can be taken on an empty stomach. If this medicine upsets your stomach, you can take it with food or immediately after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Your doctor will monitor your treatment to make sure the medicine is working and to prevent unwanted side effects.

If you forget to take it

If it is almost time to take your next dose, 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 your medicine as you would normally.

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

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

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

If you have trouble remembering 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 that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much diclofenac, you may experience vomiting, diarrhoea, bleeding from the stomach or bowel, dizziness, ringing in the ears and/or convulsions (fits).

While you are taking this medicine

Things you must do

If you are going to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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

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

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you get an infection while using diclofenac, 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.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor will monitor your treatment to make sure the medicine is working and to prevent unwanted side effects.

If you take diclofenac 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.

Your doctor will periodically re-evaluate whether you should continue treatment with diclofenac, 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 diclofenac 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.

Things you must not do

Do not take any of the following medicines while you are using diclofenac without first telling your doctor:

- aspirin
- other medicines containing diclofenac
- any other NSAID medicines

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

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

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

Diclofenac may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive, use machines, or do anything else that could be dangerous.

Patients with established cardiovascular disease or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in the blood, diabetes, or that smoke should not increase the dose above 100 mg per day if treated for more than 4 weeks.

This may increase your risk of unwanted cardiovascular events. Your doctor can discuss with you the risks and benefits involved.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 the following lists of 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, vomiting, indigestion, cramps, loss of appetite or 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)
- constipation or diarrhoea
- sore mouth or tongue

- altered taste sensation
- headache
- giddiness (vertigo) or dizziness
- skin rashes or itching
- hair loss or thinning

The above list includes the more common side effects. They are usually mild and short-lived.

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

- drowsiness, disorientation or forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods
- shakiness, sleeplessness or nightmares
- tingling or numbness of the hands or feet
- feeling of fast and irregular heartbeat
- sharp pains in your abdomen
- 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 usual
- skin inflammation with flaking or peeling
- visual impairment, including blurred or double vision
- buzzing or ringing in the ears or difficulty hearing
- high blood pressure
- hair loss or thinning

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

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

- 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)
- wheezing, troubled breathing, or feelings of tightness in the chest (signs of asthma)
- liver problems such as nausea, loss of appetite, tiredness, vomiting, pain in the upper right abdomen, yellow skin and/or eyes, dark urine, pale faeces (signs of liver problems)

- 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 blood problem such as persistent flu-like symptoms (sore throat, fever, swollen glands, aches), or bleeding or bruising more than normal
- sudden and severe headache, and/or nausea, stiff neck, dizziness, numbness, problems speaking, paralysis or convulsions/fits (possible signs of stroke or brain problem)
- 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)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- fainting
- convulsions (fits)
- chest pain (possible sign of a heart attack), difficulty breathing, weakness, slurring of speech (possible sign of a stroke)
- red or purple skin (possible signs of blood vessel inflammation)

- coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome)
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

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

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

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

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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

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

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Diclofenac looks like

APO-Diclofenac 25 mg Tablets:

Brown yellow film coated tablet, biconvex with an intact surface and uniform colour. AUST R 160729.

Blister packs of 50 tablets.

APO-Diclofenac 50 mg Tablets:

Brown yellow film coated tablet, biconvex with facet on both sides, intact surface and uniform colour. AUST R 160730.

Blister packs of 50 tablets.

*Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 25 or 50 mg of diclofenac as the active ingredient.

In addition, the tablets contain the following inactive ingredients:

- lactose monohydrate
- calcium hydrogen phosphate dihydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- colloidal anhydrous silica
- methacrylic acid copolymer
- triethyl citrate

- purified talc
- titanium dioxide
- iron oxide yellow.

This medicine is gluten-free, sucrose-free, tartrazine-free and other azo dyes-free.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

Tel: +61 2 8877 8333

Web: www1.apotex.com/au

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was last updated in November 2019.