

Diclofenac Sandoz[®]

diclofenac sodium enteric-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Diclofenac Sandoz.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.sandoz.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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 DICLOFENAC SANDOZ IS USED FOR

This medicine is used to treat:

- inflammatory and degenerative forms of rheumatism, rheumatoid arthritis and osteoarthritis

- relief of acute or chronic pain states in which there is an inflammatory component
- symptoms of menstrual pain (period pain).

It contains the active ingredient diclofenac sodium.

Diclofenac sodium belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

It works by reducing pain and inflammation (swelling and redness).

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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

There is not enough information to recommend the use of Diclofenac Sandoz tablets in children.

BEFORE YOU TAKE DICLOFENAC SANDOZ

When you must not take it

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

- diclofenac sodium, the active ingredient, or to other medicines containing diclofenac (e.g. Voltaren Emulgel) or to any of the other ingredients listed at the

end of this leaflet under Product Description.

- any other similar medicines, such as aspirin, ibuprofen or other NSAIDs.

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.

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 take Diclofenac Sandoz, these symptoms may be severe.

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

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

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

It may affect your developing baby if you take it during the last three months of pregnancy.

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.

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.

Your doctor will want to know if you are prone to allergies, especially if you get skin reaction 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, peripheral arterial disease or atherosclerotic cardiovascular disease), as treatment with diclofenac 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 diclofenac, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- a past history of ulcers (stomach or intestinal)
- 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

- 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 diclofenac 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 are breast-feeding.

Like most NSAID medicines, Diclofenac Sandoz is not recommended for use during pregnancy or breast-feeding. Use of NSAIDs may increase the risk of miscarriage particularly when taken close to the time of conception. As with other NSAIDs, use of this medicine during the third trimester of pregnancy is contraindicated due to the possibility of uterus not contracting properly, fetal kidney complications and other fetal complications. Your doctor will

discuss with you the benefits and risks of taking it.

Do not use Diclofenac Sandoz during the first 6 months of pregnancy, except on doctor's advice and it must not be used during the last 3 months. Diclofenac Sandoz may also reduce fertility and affect your chances of becoming pregnant. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

Breastfeeding is not recommended while you are using this medicine. The active ingredient in Diclofenac Sandoz passes into breast milk and may affect your baby.

Tell your doctor if you are lactose intolerant.

Diclofenac Sandoz tablets contain lactose.

Tell your doctor if you currently have an infection.

If you use Diclofenac Sandoz while you have an infections, 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 allergic to any other medicines, foods, dyes or preservatives.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Diclofenac Sandoz.

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 Sandoz may interfere with each other. These include:

- other anti-inflammatory medicines e.g. aspirin, salicylates, or ibuprofen
- warfarin or other “blood thinner” (medicines used to prevent blood clotting)
- digoxin, a medicine used to treat heart problems
- lithium or selective serotonin-reuptake inhibitors (SSRIs), medicines 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 medicines used in patients who have received organ transplants)
- trimethoprim used to 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 take

different medicines while you are using Diclofenac Sandoz.

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

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

HOW TO TAKE DICLOFENAC SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

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

In period pain, the usual starting dose is 50 mg to 100 mg per 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 increased over several menstrual cycles up to a maximum of 200 mg per day.

Do not exceed the recommended dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Diclofenac Sandoz may not work as

well and your problem may not improve.

How to take it

Diclofenac Sandoz 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.

These tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines, where they can start to work. If you chew them, the coating is destroyed.

When to take Diclofenac Sandoz

It is recommended to take the tablets before meals. You may take them with, or immediately after food in order to reduce the chance of stomach upset.

How long to take Diclofenac Sandoz

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

This medicine helps to control your condition but does not cure it.

Do not use Diclofenac Sandoz for longer than your doctor says.

If you are using Diclofenac Sandoz 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

Take your dose as soon as you remember, and continue to take it as you would normally.

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 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 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Diclofenac Sandoz. 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
- convulsions (fits).

WHILE YOU ARE TAKING DICLOFENAC SANDOZ

Things you must do

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

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

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

It can slow down blood clotting and affect kidney function.

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

Your doctor can discuss with you the risk of using it while you are pregnant.

Tell your doctor if you get an infection while taking this medicine.

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

Your doctor will periodically re-evaluate whether you should continue treatment, 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 do some tests (check your kidneys, liver and blood) from time to time to prevent unwanted side effects.

If, at any time while taking Diclofenac Sandoz 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 get an infection while using Diclofenac Sandoz, 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.

Things you must not do

Do not take any of the following medicines while you are taking Diclofenac Sandoz without first telling your doctor:

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

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

If you need to take something for headache or fever, it is usually okay to 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 take Diclofenac Sandoz 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.

Things to be careful of

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

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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

Elderly patients may be more sensitive to the effects of Diclofenac Sandoz than other adults.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking

Diclofenac Sandoz.

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 old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

Do not be alarmed by the following list 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 (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 fast or irregular heart beat

- unusual weight gain or swelling of 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 of the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning.

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

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your 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 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 like 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 generally feeling 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), fainting, convulsions/seizures (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 pains (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).

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 else that is making you feel unwell.

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

AFTER TAKING DICLOFENAC SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Diclofenac Sandoz 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Diclofenac Sandoz tablets come in two strengths:

Diclofenac Sandoz 25 mg - Brown yellow, biconvex with an intact surface and uniform colour enteric-coated tablets.

Diclofenac Sandoz 50 mg - Brown yellow, biconvex with facet on both sides, intact surface and uniform colour enteric-coated tablets.

Available in blisters or bottles of 50 tablets.

Not all strengths or presentations may be available

Ingredients

Active ingredients:

- Diclofenac Sandoz 25 mg – 25 mg diclofenac sodium
- Diclofenac Sandoz 50 mg – 50 mg diclofenac sodium

Inactive ingredients:

- Lactose monohydrate
- calcium hydrogen phosphate dihydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- colloidal silicon dioxide
- methacrylic acid copolymer
- triethyl citrate
- purified talc
- titanium dioxide
- yellow ferric oxide.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd

ABN 60 075 449 553

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Macquarie Park, NSW 2113

Australia

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New Zealand

Tel: 0800 354 335

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Australian Register Numbers:

Diclofenac Sandoz 25 mg - AUST R 63664 (blisters)

Diclofenac Sandoz 25 mg - AUST R 61297 (bottles)*

Diclofenac Sandoz 50 mg - AUST R 63661 (blisters)

Diclofenac Sandoz 50 mg - AUST R 61298 (bottles)*

* Not registered in New Zealand