

Viclofen® Tablets

diclofenac sodium tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Viclofen Tablets.

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 or pharmacist 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 VICLOFEN TABLETS ARE USED FOR

Viclofen Tablets belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to relieve pain and

reduces inflammation (swelling and redness).

It is used for short-term treatment of the following conditions:

- 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).

It contains the active ingredient diclofenac sodium.

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

Ask your doctor or pharmacist if you have any questions about this medicine.

This medicine is not addictive.

BEFORE YOU TAKE VICLOFEN TABLETS

When you must not take it

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

- diclofenac sodium, the active ingredient or any of the inactive ingredients listed at the end of this leaflet under Product Description
- other medicines containing diclofenac
- aspirin
- any other NSAID.

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 you use diclofenac, these symptoms may be severe.

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

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

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.

Use of this medicine during the last three 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 breastfeed if you are taking this medicine.

The active ingredient in Viclofen Tablets passes into breast milk and there is a possibility that your baby may be affected.

Viclofen Tablets should not be taken by children.

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 or pharmacist.

Before you start to take it

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

- liver or kidney function problems
- currently suffering from any infection
- 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
- severe attacks of indigestion, or any other stomach or bowel disorder in the past (e.g. Crohn's disease, ulcerative colitis)
- a rare liver condition called porphyria
- asthma or any other lung disease that causes difficulty in breathing
- seasonal allergies (e.g. hay fever)
- repeated chest infection
- polyps in the nose
- diabetes
- recent major surgery

- a tendency to bleed or other blood problems such as anaemia
- history of haemorrhoids (piles) or irritation of the rectum (back passage)
- any other problems with your heart or blood vessels, including disease of the heart with shortness of breath, and swelling of the feet or lips due to fluid build-up; high blood pressure or significant risk of high level of fat in your blood, diabetes or if you smoke, as treatment with Viclofen Tablets is not recommended, and if your doctor decides to prescribe Viclofen Tablets you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks
- dehydration (e.g. due to sickness, diarrhoea, before or after recent major surgery)
- swollen feet.

It is generally important to take the lowest dose that relieves your pain and/ or swelling and for the shortest time possible in order to keep your risk for heart problems or high blood pressure as small as possible.

Tell your doctor or pharmacist if you are pregnant or plan on becoming pregnant or are breastfeeding.

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

Tell your doctor or pharmacist if you are lactose intolerant.

Viclofen Tablets contain lactose monohydrate.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Viclofen Tablets.

Taking other medicines

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

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

- aspirin, salicylates or other anti-inflammatory (NSAID) medicines
- lithium or selective serotonin-reuptake inhibitors (SSRIs), a medicine used to treat some types of depression
- digoxin, a medicine for your heart
- diuretics, also called fluid or water tablets
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)
- antidiabetic agents for diabetes
- methotrexate, a medicine used for treatment of rheumatoid arthritis, as well as some types of cancers
- cyclosporin, tacrolimus (a medicine used to suppress the immune system)
- certain antibiotics called quinolones
- glucocorticoid medicines, used to treat arthritis
- ACE inhibitors or beta-blockers, medicines used to treat high blood pressure, heart conditions, glaucoma and migraine
- corticosteroids, medicines such as prednisone and cortisone, which reduce the activity of your immune system
- antacids used for indigestion. You can still take these medicines while you are taking Viclofen Tablets. However, you must take Viclofen Tablets at least 1 hour before or 2 hours after taking any antacid to make sure there is no problem with absorption.

- sulfinpyrazone (a medicine used to treat gout)
- rifampicin, a medicine used to treat variety of infections
- voriconazole, a medicine used to treat fungal infections
- phenytoin (a medicine used to treat seizures)
- trimethoprim (a medicine used to treat urinary tract infections).

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

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

HOW TO TAKE VICLOFEN TABLETS

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

Adults

The usual dosage is one or two tablets two to three times a day when necessary. Not recommended for use in children.

Do not take more than eight tablets in 24 hours.

How to take it

The tablets should be swallowed whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them from dissolving until they have gone through the stomach into the bowel. If you chew them, the coating is destroyed.

When to take Viclofen Tablets

Take your medicine with or immediately after a meal.

If you take it on an empty stomach, it may cause stomach upset.

How long to take Viclofen Tablets

Viclofen Tablets are for short term use only.

If pain persists for more than 3 days, please see your doctor.

If you forget to take it

Viclofen Tablets should only be taken when necessary. It should not be taken on a regular basis.

Do not take a double dose to make up for the one 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 take too much (overdose)

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

You may need urgent medical attention.

Symptoms of an overdose may include: nausea, vomiting, gastrointestinal haemorrhage, diarrhoea, abdominal pain, drowsiness, tinnitus (ringing in the ears) or convulsions, headache, dizziness and blurred vision.

WHILE YOU ARE TAKING VICLOFEN TABLETS

Things you must do

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

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

If at any time while taking Viclofen Tablets, 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.

Tell your doctor or pharmacist if you become pregnant or plan on becoming pregnant or breastfeeding while taking Viclofen Tablets.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. NSAID medicines can slow down blood clotting and affect kidney function.

If you get an infection while taking Viclofen Tablets, tell your doctor or pharmacist.

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 Viclofen Tablets to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours.

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

- aspirin (also called ASA or acetylsalicylic acid), or other salicylates

- other medicines containing diclofenac
- ibuprofen
- any other NSAID medicine.

If you take these medicines together with Viclofen Tablets, 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.

Things to be careful of

Be careful driving or operating machinery until you know how Viclofen Tablets affects you.

This medicine may cause dizziness, drowsiness, light-headedness, spinning sensation (vertigo) or blurred vision 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 this medicine than other adults.

SIDE EFFECTS

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

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.

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.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor or pharmacist.

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

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

- stomach or abdominal pain, abdominal cramps, wind, indigestion, loss of appetite
- 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)
- nausea (feeling sick), vomiting
- constipation, diarrhoea
- sore mouth or tongue
- altered taste sensation
- anorexia
- rashes
- dizziness, spinning sensation (vertigo)
- 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
- blurred or double vision
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)

- hair loss or thinning
- visual disturbances like impairment, blurred vision
- headache.

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

If any of the following happen, stop taking Viclofen Tablets, and tell your doctor or pharmacist immediately, or go to accident and emergency at your nearest hospital:

- signs of possible blood vessel inflammation such as red or purple skin
- signs of possible stomach problems such as 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
- signs of allergy such as: 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), shortness of breath, wheezing, troubled breathing, or feelings of tightness in the chest
- peptic ulceration and gastrointestinal bleeding may occur in some patients. If you feel unusually weak and tired, or notice blood in your faeces, together with severe stomach pain, stop taking the tablets and see your doctor immediately.
- signs of liver problem such as persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper abdomen, yellowing of skin and/or eyes, dark urine or pale bowel motions
- signs of a possible blood problem such as constant "flu-like" symptoms (chills, fever,

- sore throat, aching joints, swollen glands, tiredness or lack of energy), bleeding or bruising more easily than normal
- signs of 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.
 - signs of a possible effect on brain, such as sudden and severe headache, stiff neck, severe nausea, dizziness, numbness, difficulty in speaking, paralysis, convulsions (fits)
 - signs of possible kidney disorders such as a change in the colour or amount of urine passed, frequent need to urinate, burning feeling when passing urine, blood in the urine or excess protein in the urine
 - fainting or seizures (fits)
 - signs of cardiac failure such as breathlessness, difficulty breathing when lying down, swelling of the feet or legs
 - chest pain, which may be a sign of a heart attack.

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 VICLOFEN TABLETS

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 Viclofen Tablets or any other medicine in the bathroom or near a sink. Do not

leave it on a window sill or in a 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

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Viclofen Tablets 25mg - round, brown-yellow enteric coated tablets.

Available in blisters of 20 and 30 tablets.

Ingredients

Active ingredients:

Viclofen Tablets 25mg - 25mg 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
- talc
- titanium dioxide (E171)
- yellow ferric oxide (E172, CI 77492).

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

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road

Macquarie Park, NSW 2113
Australia

Tel: 1800 634 500

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25mg tablets: AUST R 75245
(blisters)