

Voltaren[®]

Rapid 12.5

Diclofenac potassium 12.5 mg
film-coated tablets



What is in this leaflet

This leaflet answers some common questions about Voltaren Rapid 12.5.

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

All medicines have risks and benefits. Your pharmacist or doctor can advise you about the risks and benefits of taking Voltaren Rapid 12.5.

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

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

What Voltaren Rapid 12.5 is used for

Voltaren Rapid 12.5 provides temporary relief from headache, dental pain, period pain, rheumatic and muscular pain, and backache. It also provides temporary relief of symptoms of colds and flu (including aches and pains, sore throat pain) and reduces fever.

Voltaren Rapid 12.5 belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Like all NSAIDs, Voltaren Rapid 12.5 is a pain reliever which also reduces inflammation (swelling) and lowers temperature.

Before you take Voltaren Rapid 12.5

When you must not take it

Do not take Voltaren Rapid 12.5 if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in Voltaren Rapid 12.5), or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac (e.g. Voltaren tablets or suppositories, Voltaren Emulgel, Volfast powder)
- aspirin
- any other anti-inflammatory medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or anti-inflammatory medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Some of the symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

If you are allergic to aspirin or anti-inflammatory medicines and take Voltaren Rapid 12.5, these symptoms may be severe.

Do not give this medicine to a child under 14 years of age.

There is not enough information on the use of Voltaren Rapid 12.5 in children under that age.

Do not take Voltaren Rapid 12.5 if you:

- currently have stomach or intestinal ulcer, or other stomach disorder
- have bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- have impaired kidney function or severe liver disease
- have heart failure.

Do not take Voltaren Rapid 12.5 during the last 3 months of pregnancy.

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

Do not take Voltaren Rapid 12.5 after the expiry date printed on the pack.

Do not take Voltaren Rapid 12.5 if the foil seal over the tablets has been broken or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should start taking Voltaren Rapid 12.5, talk to your pharmacist or doctor.

Before you start to take it

Talk to your doctor before taking Voltaren Rapid 12.5 if you:

- have asthma or any other chronic lung disease that causes difficulty in breathing.

Talk to your doctor or pharmacist before taking Voltaren Rapid 12.5 if you have or have had any medical conditions, especially the following:

- 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 a history of blood vessel disease
- significant risk factors for heart disease, such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes or if you smoke
- history of ulcers (stomach or intestinal)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools (vomiting blood or bleeding from the back passage)
- stomach discomfort or heartburn after taking pain relievers or anti-inflammatory medicines
- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative colitis)
- liver or kidney problems
- a rare condition called hepatic porphyria
- bleeding disorders or other blood disorders such as anaemia
- diabetes
- dehydration (eg by sickness, diarrhoea, before or after recent major surgery)
- swollen feet.

Do not exceed the recommended dose.

Treatment with anti-inflammatory medicines, such as diclofenac, may be associated with an increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. If you have existing heart disease or risk factors for heart disease, you may be at greater risk.

It is generally important to take the lowest dose of Voltaren 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 pharmacist or doctor if you are pregnant or trying to become pregnant.

Unless a doctor has told you to, do not use Voltaren Rapid during the first 6 months of pregnancy. Do not use Voltaren Rapid 12.5 at all during the last 3 months of pregnancy.

Tell your pharmacist or doctor if you are breastfeeding.

Unless a doctor has told you to, do not use Voltaren Rapid 12.5 during breastfeeding.

Tell your pharmacist or doctor if you are allergic to any other medicines, foods, dyes or preservatives.

They will want to know if you are prone to allergies.

Tell your pharmacist or doctor if you are sensitive to lactose.

One Voltaren Rapid 12.5 tablet contains 33.5 mg lactose. When taken as recommended, each dose supplies up to 67 mg lactose.

Tell your pharmacist or doctor if you currently feel unwell or have an infection.

Voltaren Rapid 12.5 may hide some of the signs of an infection (pain, fever, swelling, redness) and you may think, mistakenly, that you are better or that the infection is not serious.

If you have not told your pharmacist or doctor about any of the above, tell them before you take Voltaren Rapid 12.5.

Taking other medicines

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

Some medicines that are important to mention include:

- other anti-inflammatory medicines eg aspirin, salicylates or ibuprofen
- lithium or selective serotonin-reuptake inhibitors (SSRIs), medicines used to treat depression
- digoxin, a medicine used to treat heart problems
- ACE inhibitors or beta-blockers, medicines used to treat high blood pressure or heart conditions, glaucoma and migraine
- diuretics, also called fluid or water tablets, used to increase the amount of urine
- medicines used to treat diabetes, except insulin
- prednisone, cortisone or other corticosteroids, medicines used to provide relief for inflamed areas of the body



- warfarin, other blood thinners or anticoagulants, medicines used to prevent blood clotting
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin or tacrolimus, medicines in patients who have received organ transplants
- trimethoprim, a medicine used to prevent or treat urinary tract infection
- quinolone antibacterials, medicines used to treat infections
- sulfapyridazine, a medicine used to treat gout
- voriconazole, a medicine used to treat fungal infections
- phenytoin, a medicine used to treat seizures

These medicines may be affected by Voltaren Rapid 12.5 or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medications.

Your pharmacist and doctor have more information on medicines to be careful with or to avoid while taking Voltaren Rapid 12.5.

How to take Voltaren Rapid 12.5

How much to take

Ask your pharmacist or doctor 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.

Do not take more than the recommended dose.

Take the lowest dose of Voltaren Rapid 12.5 that relieves your pain and/or swelling.

Stop taking as soon as your symptoms are relieved. Do not take for longer than a few days at a time.

Adults and children aged 14 years and over: Take an initial dose of 2 tablets when symptoms appear. If needed, continue with 1 or 2 tablets every 4 to 6 hours.

Do not take more than 6 tablets in 24 hours.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take the tablets on an empty stomach (at least half an hour before food or two hours after food).

They will work more quickly if you take them on an empty stomach.

If they upset your stomach, take the tablets with food.





They will still work if you have to take them with food to prevent stomach upset.

How long to take it

Do not take Voltaren Rapid 12.5 for more than a few days without consulting your doctor.

If symptoms persist or worsen, see your pharmacist or doctor to ensure that they are not due to a serious illness. The use of Voltaren Rapid 12.5 could mask potentially serious infections.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Australia 131 126, New Zealand 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Voltaren Rapid 12.5.

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

You may need urgent medical attention.

While you are taking Voltaren Rapid 12.5

Things you must do

If you become pregnant while taking

Voltaren Rapid 12.5, tell your pharmacist or doctor immediately.

They can discuss with you the risks of using it while you are pregnant.

If, at any time while taking Voltaren Rapid 12.5 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.

If you are about to start taking any new medicine, tell your pharmacist and doctor that you are taking Voltaren Rapid 12.5.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Voltaren Rapid 12.5.

If you are going to have surgery, tell the surgeon and the anaesthetist that you are taking Voltaren Rapid 12.5.

Anti-inflammatory medicines can slow down blood clotting and affect kidney function.

If you get an infection while taking Voltaren Rapid 12.5, tell your pharmacist or 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 Voltaren Rapid 12.5 without first telling your doctor or pharmacist:

- aspirin or other salicylates
- other medicines containing diclofenac
- any other anti-inflammatory medicine.

If you take these medicines together with Voltaren Rapid 12.5, they may cause unwanted side effects.

Do not use Voltaren Rapid 12.5 to treat any other complaints, unless your pharmacist or doctor tells you to.

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

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Voltaren Rapid 12.5 affects you.

As with other anti-inflammatory medicines, Voltaren Rapid 12.5 may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people.

Be careful if you are older than 65 years of age.

Older people may be more sensitive to the effects of Voltaren Rapid 12.5 than other adults. Take the lowest number of tablets that provides relief of symptoms, and report side effects promptly to your doctor or pharmacist.

Side effects

All medicines may have some unwanted 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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Voltaren Rapid 12.5.

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

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

Tell your pharmacist or doctor if you notice any of the

following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, heartburn, 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 heartbeat, also called palpitations
- unusual weight gain or mild swelling
- symptoms of sunburn (such as redness, itching, swelling, blistering of the lips, eyes, mouth and/or skin) that happen more quickly than normal
- vision disorders (eg blurred or double vision)
- buzzing or ringing in the ears, difficulty hearing
- hypertension (high blood pressure)
- hair loss or thinning

Tell your doctor or pharmacist immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- red or purple skin (possibly 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)
- sudden or severe itching, 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, coughing, sudden difficulty in 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 possible effects of 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), convulsion (fits)
- a 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).

These are very serious side effects. Some of these side effects are signs of a serious allergic reaction. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

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

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

After using Voltaren Rapid 12.5

Storage

Keep your tablets in the original packaging until it is time to take them.

If you take the tablets out of the box or blister pack, they may not keep well.

Store the tablets in a cool dry place where the temperature stays below 30 °C. Do not store Voltaren Rapid 12.5 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window-sills.

Heat and dampness can destroy some medicines.

Keep the medicine 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 pharmacist or doctor tells you to stop taking Voltaren Rapid 12.5, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist for safe disposal.

Product description

What it looks like

Voltaren Rapid 12.5 are small, easy-to-swallow, white tablets.

Ingredients

Voltaren Rapid 12.5 contains 12.5 mg of diclofenac potassium as the active ingredient in each tablet. They also contain: silica – colloidal anhydrous, lactose, starch - maize, sodium starch glycolate, povidone, magnesium stearate, hypromellose, titanium dioxide, stearic acid and cellulose - microcrystalline.

Sponsor

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