

Voltaren[®] Rapid

diclofenac potassium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Voltaren Rapid.

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.novartis.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 provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Voltaren Rapid is used for

Voltaren Rapid belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAID). It relieves pain and reduces inflammation (swelling and redness).

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

- migraine headaches and it may also relieve the accompanying symptoms, such as nausea and vomiting, which you sometimes experience when you have a migraine
- relief of menstrual cramps (period pain).
- short-term treatment (up to 1 week) of other painful conditions where swelling is a problem such as back or joint pain, dental pain, muscle strains or sprains and tendonitis (e.g. tennis elbow).

Voltaren Rapid 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 purpose.

Voltaren Rapid is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend this medicine for children and adolescents under 14 years of age.

Before you take Voltaren Rapid

When you must not take it

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

- diclofenac (the active ingredient in Voltaren Rapid) 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, Voltfast powder)
- aspirin
- ibuprofen
- any other NSAID

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

Some of the symptoms of an allergic reaction 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 take Voltaren Rapid, these symptoms may be severe.

Do not take Voltaren Rapid 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 Voltaren Rapid 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 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 Voltaren Rapid after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have any of the following health problems / 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 Voltaren 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 Voltaren, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- 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)
- 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 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 doctor if you are pregnant or trying to become pregnant.

There is not enough information to recommend the use of Voltaren Rapid during the first 6 months of pregnancy and it must not be used during the last 3 months.

Voltaren Rapid 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 currently have an infection.

If you take Voltaren Rapid 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 breast-feeding.

Breast-feeding is not recommended while you are using this medicine. The active ingredient in Voltaren Rapid passes into breast milk and may affect your baby.

Tell your doctor if you are fructose intolerant.

This medicine contains sucrose, which is converted by the liver to fructose.

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.

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 that are important to mention 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 your 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)
- cyclosporin, 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 taking Voltaren Rapid. 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 taking this medicine.

How to take Voltaren Rapid

Swallow the Voltaren Rapid tablets whole with a full glass of water. Do not break them or chew them.

When to take it

Take the tablets preferably before meals. 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 Voltaren Rapid 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 on the label, ask your doctor or pharmacist for help.

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

Do not exceed the recommended dose.

To treat migraine

The usual dose is 50 mg (one tablet) at the first sign of an attack. If the pain is not relieved within 2 hours, another tablet can be taken. After that, you must wait at least 4 hours before taking any more Voltaren Rapid.

Do not take more than 200 mg (4 tablets) in 24 hours even if you have more than one migraine attack within that 24 hour period.

To treat menstrual cramps (period pain)

The usual dose is 50 mg to 100 mg (1 to 2 tablets) beginning as soon as cramps begin. This is usually followed by 1 tablet three times each day until the pain goes away, but for no longer than 3 days.

To treat other painful conditions

The usual dose is 100 mg to 150 mg (2 to 3 tablets) each day. In milder cases, as well as in children over 14 years old, 75 mg to 100 mg each day is usually enough.

How long to take it

Do not take Voltaren Rapid for longer than your doctor says.

It is usually taken for a short time only (up to one week) but it may be prescribed on repeated occasions, depending on your condition.

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 the 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 one that 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 Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Voltaren Rapid. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If you take too much Voltaren Rapid, you may experience:

- vomiting
- bleeding from the stomach or bowel
- diarrhoea
- dizziness
- ringing in the ears
- convulsions (fits)

While you are taking Voltaren Rapid

Things you must do

If you become pregnant while taking Voltaren Rapid, tell your doctor immediately.

Your doctor can discuss with you the risks of taking it 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 Voltaren, 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 Voltaren 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, make sure the surgeon and anaesthetist know that you are taking Voltaren Rapid.

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

If you get an infection while taking Voltaren Rapid, 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 Voltaren Rapid.

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

Things you must not do

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

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

- other medicines containing diclofenac (e.g. Voltaren tablets or suppositories, Voltaren Emulgel, Voltfast powder)
- ibuprofen
- any other NSAID medicine

If you take these medicines together with Voltaren Rapid, 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 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 Voltaren Rapid affects you.

This medicine 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 carry out other activities that need careful attention.

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 Voltaren Rapid than other adults.

Side effects

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

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 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 these lists 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 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 Voltaren Rapid, 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 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 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 if you notice anything else that is making you feel unwell.

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

After using Voltaren Rapid

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Voltaren Rapid or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

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 doctor tells you to stop taking Voltaren Rapid or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Voltaren Rapid 50 mg tablets are reddish-brown sugar-coated tablets; blister packs of 20 tablets.

Ingredients

Voltaren Rapid tablets contain 50 mg diclofenac potassium as the active ingredient. They also contain:

- silica colloidal anhydrous
- calcium phosphate (E341)
- magnesium stearate (E572)
- maize starch
- povidone (E1201)
- sodium starch glycolate
- microcrystalline cellulose (E460)
- iron oxide red CI77491 (E172)

- macrogol 8000
- sucrose
- purified talc (E553b)
- titanium dioxide (E171)

Voltaren Rapid does not contain lactose, gluten, tartrazine or any other azo dyes.

Sponsor

Voltaren Rapid is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

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