





Voltaren

Rapid EXTRA STRENGTH

Diclofenac potassium 25 mg



WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Voltaren Rapid Extra Strength.

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 has weighed the risks of you taking this medicine against the benefits they expect it will provide.

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 EXTRA STRENGTH IS USED FOR

Voltaren Rapid Extra Strength relieves pain and reduces inflammation (swelling and redness). It can be used for:

- the short-term treatment (up to 3 days) of painful conditions where swelling is a problem, such as back or joint pain, dental pain, muscle strains, sprains or tendinitis (eg. tennis elbow)
- the relief of menstrual cramps (period pain)
- the relief of migraine headaches. It may also relieve nausea and vomiting sometimes experienced with a migraine.

Voltaren Rapid Extra Strength belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines can relieve the symptoms of pain and inflammation but they will not cure your condition.

Voltaren Rapid Extra Strength is not addictive.

BEFORE YOU TAKE VOLTAREN RAPID EXTRA STRENGTH

When you must not take it

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

- diclofenac (the active ingredient in Voltaren Rapid Extra Strength), or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- 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 Extra Strength, 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 Extra Strength in children under that age.

Do not take Voltaren Rapid Extra Strength if you:

- currently have a stomach or intestinal ulcer or other stomach disorders
- 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
- are trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all 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. Use of this medicine can increase the risk of miscarriage, particularly when taken close to the time of conception.

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

Do not take Voltaren Rapid Extra Strength 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 Extra Strength, talk to your pharmacist or doctor.

Before you start to take it

Talk to your doctor before taking Voltaren Rapid Extra Strength 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 Extra Strength 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 ischaemic 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 liver 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 Rapid Extra Strength 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 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 fructose intolerant.

Voltaren Rapid Extra Strength contains sucrose, which is converted by the liver to fructose.

Tell your pharmacist or doctor if you have an infection at the present time.

If you take Voltaren Rapid Extra Strength while you have an infection, some of the signs of the infection may be hidden (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that the infection is not serious.

Tell your pharmacist or doctor if you are pregnant, think you may be pregnant or trying to become pregnant.

Unless absolutely necessary and unless advised by your doctor, do not use Voltaren Rapid Extra Strength during the first 6 months of pregnancy. Use of Voltaren Rapid Extra Strength after 20 weeks of pregnancy may lead to kidney problems in your unborn baby. This could reduce the amount of fluid that surrounds the baby which can be harmful. Do not use 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 Extra Strength during breastfeeding.

If you have not told your pharmacist or doctor about any of these things, tell him/her before you take Voltaren Rapid Extra Strength.

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, 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 used in patients who have received organ transplants
- certain antibiotics called quinolones or trimethoprim, used to treat infections
- glucocorticoid, medicines used to treat arthritis
- sulfapyrazole, 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 Extra Strength 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 Extra Strength.

HOW TO TAKE VOLTAREN RAPID EXTRA STRENGTH

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

These instructions may differ from the information contained in this leaflet.

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

How much to take

Do not take more than the recommended dose. Take the lowest dose of Voltaren Rapid Extra Strength that relieves your pain and/or swelling.

Stop taking as soon as your symptoms are relieved.

For most painful conditions:

Do not take for longer than 3 days at a time unless on the advice of a healthcare professional.

Adults: (According to pain) Take 1-2 tablets initially, followed by 1-2 tablets at 8 hourly intervals.

Children over 14 years: Take 1-2 tablets initially, followed by 1 tablet at 8 hourly intervals.

For menstrual pain (period pain):

Take 2 tablets at the first sign of symptoms, then 2 tablets up to 3 times daily for the next 3 days if required.

For migraine:

Take 2 tablets at the first sign of a migraine attack. If the pain is not relieved within 2 hours, a further 1 to 2 tablets may be taken. After that dose, you must wait at least 4 hours before taking any more Voltaren Rapid Extra Strength.

For migraine attack, do not take more than 8 tablets even if you have more than one migraine attack within that 24 hour period.

Do not take more than 8 tablets in 24 hours, for relief of any of the above conditions. Do not take for longer than 3 days at a time unless on the advice of a healthcare professional.

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

How to take it

Swallow the tablets with a full glass of liquid.

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.

Do not lie down for about 15 to 30 minutes after taking the tablets. This helps them reach your stomach quickly and prevents throat irritation, which could lead to problems with swallowing.

How long to take it

Do not take Voltaren Rapid Extra Strength for more than 3 days at a time unless a doctor has told you to. It is usually taken for a short time only.

For menstrual cramps (period pain), the tablets are usually taken during each period as soon as cramps begin and continued for up to 3 days until the pain goes away.

If you forget to take it

If it is almost time for your next dose (eg. 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. If you are not sure what to do, ask your pharmacist or doctor.

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 you or anyone else may have taken too much Voltaren Rapid Extra Strength.

Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

You may need urgent medical attention.

WHILE YOU ARE TAKING VOLTAREN RAPID EXTRA STRENGTH

Things you must do

If you become pregnant while taking Voltaren Rapid Extra Strength, tell your pharmacist or doctor immediately. He/she can discuss with you the risks of using it while you are pregnant.

If, at any time while taking Voltaren Rapid Extra Strength 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 be started on any new medicine, remind your pharmacist and doctor that you are taking Voltaren Rapid Extra Strength.

Take Voltaren Rapid Extra Strength exactly as directed by your pharmacist or doctor.

If you do not follow these instructions, your condition may not improve or you may have unwanted side effects.

If, for any reason, you have not taken your medicine exactly as directed or as described in this leaflet, tell your pharmacist or doctor. Otherwise, he/she may think that it was not effective and change your treatment unnecessarily.

If you feel the medicine is not helping, tell your pharmacist or doctor. This will help him/her to determine the best treatment for you.

If you are going to have surgery, make sure the surgeon and the anaesthetist know that you are taking Voltaren Rapid Extra Strength.

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

If you get an infection while taking Voltaren Rapid Extra Strength, 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. Tell any other doctor, dentist or pharmacist who treats you that you are taking Voltaren Rapid Extra Strength.

Things you must not do

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

- aspirin or other salicylates
- other forms of Voltaren or Voltaren Rapid
- any other anti-inflammatory medicine.

If you take these medicines together with Voltaren Rapid Extra Strength, they may cause unwanted effects. If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, ask your pharmacist or doctor.

Do not use Voltaren Rapid Extra Strength to treat any other complaints, unless your pharmacist or doctor says you can.

Do not give this medicine to anyone else, even if their condition seems to be 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 Extra Strength affects you.

As with other anti-inflammatory medicines, Voltaren Rapid Extra Strength may cause dizziness, drowsiness, spinning sensation (vertigo) or blurred vision in some people. If you have any of these symptoms, do not drive or carry out other activities that need careful attention.

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

Older people may be more sensitive to the effects of Voltaren Rapid Extra Strength 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

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines 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 get an allergic reaction stop taking Voltaren Rapid Extra Strength and see your doctor immediately.

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 get side effects from medicines.

Do not be alarmed by this list 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 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 and pharmacist immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:**
- 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)
 - 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)
 - persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, dark urine or pale bowel motions (possible liver problems)
 - yellowing of the skin and/or eyes (signs of hepatitis/liver failure)
 - 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, swollen lymph nodes, facial swelling, blood abnormalities and inflammation of the liver, kidneys and other internal organs (possible serious skin reaction)
 - signs of possible effects 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)
 - 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 disorder)
 - 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 happen in some people.

AFTER USING VOLTAREN RAPID EXTRA STRENGTH

Storage

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

Store the tablets in a cool dry place where the temperature stays below 30°C.

Do not store Voltaren Rapid Extra Strength 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.

Voltaren Rapid Extra Strength will keep well if it is cool and dry.

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 Extra Strength or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Return any unused medicine to your pharmacist for safe disposal.

PRODUCT DESCRIPTION

What it looks like

Voltaren Rapid Extra Strength tablets are pale red sugar-coated tablets; blister packs of 10, 20 or 30 tablets.

Ingredients

Voltaren Rapid Extra Strength tablets contain 25 mg diclofenac potassium as the active ingredient. They also contain: silica – colloidal anhydrous, calcium phosphate (E341), magnesium stearate (E572), starch – maize, povidone (E1201), sodium starch glycollate, cellulose – microcrystalline (E460), iron oxide red C177491 (E172), macrogol 8000, sucrose, talc – purified (E553b), titanium dioxide (E171). Contains sulfites.

Haleon

Sydney, NSW, Australia

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