VOLTFAST®

Diclofenac Potassium 50mg Powder for oral solution

What is in this leaflet

This leaflet answers some common questions about Voltfast.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking it 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 Voltfast is used for

Voltfast relieves pain and reduces inflammation (swelling and redness) that may occur in the following:

- Sprains, strains, or other injuries
- Painful menstrual periods (period pain)
- Migraine attacks
- Back pain, frozen shoulder, tennis elbow and other forms of soft-tissue rheumatism
- Infections of the ear, nose or throat

Voltfast belongs to a family 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.

Your doctor may prescribe Voltfast for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

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

Before you take Voltfast

When you must not take it

Do not take Voltfast if you have an allergy to:

- diclofenac (the active ingredient in Voltfast) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac (eg. Voltaren, Voltaren Emulgel, Flameril)
- aspirin/ acetylsalicylic acid
- any other NSAID medicine

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

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 NSAID medicines and take Voltfast, these symptoms may be severe.

Do not take Voltfast if at the present time you have an ulcer (gastric or duodenal) or bleeding from the stomach or bowel.

If you take it, your stomach problem may become worse.

Do not take Voltfast if you suffer from severe kidney or liver disease or severe heart failure.

Do not take Voltfast after the expiry date (EXP) printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take Voltfast if the packaging is torn or shows signs of tampering.

Voltfast is not recommended for use in children below 14 years of age.

Do \underline{not} give Voltfast 50mg powder for oral solution to a child.

This form of Voltfast is not recommended for use in children, as there is not enough information on its use in this age group.

If you are not sure whether you should start taking Voltfast, contact your doctor.

Before you start to take it

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.

Tell your doctor if, in the past, you have ever had:

- ulcers (gastric or duodenal)
- severe attacks of indigestion or other stomach trouble
- diseases of the bowel (eg. Crohn's disease, ulcerative colitis)
- bleeding from your rectum (back passage)

Tell your doctor if you have any of these health problems/medical conditions at the present time:

- 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), as treatment with Voltfast 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 Voltfast, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- it is generally important to take the lowest dose of Voltfast 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.
- kidney disease
- liver disease
- a tendency to bleed or other blood problems such as anaemia
- asthma
- haemorrhoids (piles) or irritation of the rectum (back passage)

Your doctor may want to take special precautions if you have any of these conditions.

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

If you take Voltfast 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 doctor if you are pregnant or are breast-feeding.

Like most NSAID medicines, Voltfast is not recommended for use during pregnancy or breast-feeding. Your doctor will discuss with you the benefits and risks of taking it.

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:

- aspirin, salicylates, ibuprofen, or other NSAID medicines
- warfarin, a medicine used to stop blood clots
- · digoxin, a medicine for your heart
- lithium, a medicine used to treat some types of depression
- diuretics, also called fluid or water tablets
- tablets used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin, tacrolimius, medicines used to suppress the immune system
- trimethoprim, a medicine used to prevent or treat urinary tract infections
- certain antibiotics called quinolones
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure and heart failure)
- corticosteroids (medicines used to provide relief for inflamed areas of the body)
- sulfinpyrazone (a medicine used to treat gout)
- phenytoin (a medicine used to treat seizures).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Voltfast.

If you have not told your doctor about any of these things, tell them before you take Voltfast.

How to take Voltfast

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.

How much to take

Your doctor will assess your situation and the lowest effective dose for the shortest possible duration will be prescribed. Voltfast comes in a sachet containing 50mg of powder for oral solution.

Do not exceed the recommended dose. It is important that you use the lowest dose that controls your pain and that you do not take Voltfast for longer than necessary.

Your doctor will tell you exactly how many sachets of Voltfast to take. Depending on how you respond to the treatment.

Adults

The recommended starting dose is generally 100 to 150mg daily (to be taken in 2 to 3 doses). In milder cases 50 to 100mg daily (to be taken in 1 to 2 doses). Do not exceed 150mg per day.

Children (over 14 years of age)

The recommended dose is 50 to 100mg daily (to be taken in 1 to 2 doses). Do not exceed 150mg per day.

Voltfast should preferably be taken before meals.

Voltfast should be dissolved by stirring in a glass of non carbonated water. The solution may remain slightly cloudy, but this should not influence the efficacy of the medicine.

How long to take it

Do not take Voltfast for longer than your doctor says.

For menstrual cramps (period pain), start treatment with a single dose of 50 to 100mg as soon as you feel the first symptoms. Continue with 50mg up to three times a day for a few days as needed. If 150mg a day does not proved sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you take up to 100mg a day during your next menstrual period. Do not exceed 200mg.

In migraine, take Voltfast as the first symptoms of a migraine attack. The initial dose is 50mg. If relief is not obtained within 2 hours take a further dose of 50mg. This may be repeated at intervals of 4 to 6 hours, but you should not take more than 200mg per day.

If you take Voltfast for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

If you have questions about how long to take Voltfast, talk to your doctor or your pharmacist.

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 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 National Poisons Information Centre, Dunedin (phone 0800 POISON or 0800 764 766), or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Voltfast. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Voltfast

Things you must do

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

Your doctor can discuss with you the risks of taking it while you are pregnant.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Voltfast. Take Voltfast exactly as your doctor has prescribed.

If you do not follow your doctor's 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 prescribed, tell your doctor.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

If you feel the medicine is not helping, tell your doctor.

This will help your doctor to determine the best treatment for you.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

If you have established heart disease or significant risks for heart disease, make sure to tell your doctor.

Your doctor will periodically re-evaluate whether you should continue treatment with Voltfast, especially in case you are treated for more than 4 weeks.

If, at any time while taking Voltfast 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 going to have surgery, make sure the surgeon and anaesthetist know that you are taking Voltfast.

NSAID medicines can slow down blood clotting.

If you get an infection while taking Voltfast, 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 all of the doctors, dentists and pharmacists that are treating you that you are taking Voltfast.

Things you must not do

Do not take any other medicines used to treat arthritis while you are taking Voltfast without first telling your doctor. This includes:

- aspirin (also called ASA or acetylsalicylic acid)
- other salicylates
- other forms of Voltaren
- any other NSAID medicine

If you take these medicines together with Voltfast, 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 doctor.

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 use Voltfast to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else.

It may harm them, even if their symptoms seem to be the same as yours.

Things to be careful of

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

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As with other NSAID medicines, Voltfast may cause dizziness, drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

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

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 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 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.

Tell your 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
- constipation, diarrhoea, pain in the stomach, wind
- dizziness, light headedness
- drowsiness, sleepiness, disorientation
- buzzing or ringing in the ears
- change in mood, for example, feeling depressed, anxious or irritable
- trembling, sleeplessness, nightmares
- headache
- sore mouth or tongue
- hair loss or thinning
- altered taste sensation
- memory impairment

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal; reddish or purplish blotches under the skin
- signs of anaemia such as tiredness, being short of breath, looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- signs of a liver problem such as tiredness, lack of energy, itching of the skin, yellowing of the skin and eyes, pain in the abdomen
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- eye problems such as blurred or double vision
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- fast or irregular heart beat, also called palpitations
- difficulty hearing
- high blood pressure

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Voltfast and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital:

- sudden and oppressive chest pain (signs of myocardial infarction or heart attack)
- breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash or hives
- fainting or seizures (fits)
- pain or tightness in the chest
- inability or difficulty to speak
- paralysis (signs of cerebral attack)
- stiff neck (signs of meningitits)
- raised blood pressure

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

Some people may get other side effects of Voltfast.

After using Voltfast

Storage

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

Heat and dampness can destroy some medicines. They will keep well if the temperature 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 doctor tells you to stop taking Voltfast or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Voltfast 50mg powder for oral solution: white to light yellow powder.

Ingredients

Voltfast powder for oral solution contain 50mg diclofenac potassium as the active ingredient.

It also contains: potassium hydrogen carbonate; mannitol; aspartame; saccharin sodium; glyceryl dibehenate; mint flavour; anise flavour.

Sponsor

Voltfast is supplied in New Zealand by:

Novartis New Zealand Limited

109 Carlton Gore Road

Newmarket

Auckland 1023

PO Box 99102

Newmarket

Auckland 1149

Telephone 0800 354 335

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