Voltaren® Rapid

Tablets

Diclofenac Potassium

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Voltaren Rapid?

Voltaren Rapid contains the active ingredient Diclofenac Potassium. Voltaren Rapid is used to treat migraine headaches, period cramps or pain, short-term treatment (up to 1 week) of certain painful conditions associated with swelling e.g. back or joint pain.

For more information, see Section <u>1. Why am I using</u> <u>Voltaren Rapid?</u> in the full CMI.

2. What should I know before I use Voltaren Rapid?

Do not use if you have ever had an allergic reaction to Voltaren Rapid or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before I use Voltaren Rapid?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Voltaren Rapid and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Voltaren Rapid?

- Your doctor will advise you on the appropriate dose.
- Follow the instructions provided and use Voltaren Rapid until your doctor tells you to stop.

More instructions can be found in Section <u>4. How do I</u> <u>use Voltaren Rapid?</u> in the full CMI.

5. What should I know while using Voltaren Rapid?	
Things you should do	 Remind any doctor, dentist, pharmacist or specialist you visit that

	 you are using Voltaren Rapid. Tell your doctor immediately if you become pregnant or intend to become pregnant or if you are breastfeeding.
Things you should not do	 Do not stop using this medicine suddenly. Do not use Voltaren Rapid in children. Do not give Voltaren Rapid to anyone else, even if they seem to have the same condition as you.
Driving or using machines	 Voltaren Rapid may cause vision problems, dizziness, spinning sensation (vertigo), sleepiness or other central nervous system problems in some people. If you have the above symptoms, do not drive a vehicle or operate machines.

Drinking alcohol	 Tell your doctor if you drink alcohol.
Looking after your medicine	 Store below 30°C Keep it where young children cannot reach it.

For more information, see Section <u>5. What should I know</u> while using Voltaren Rapid? in the full CMI.

6. Are there any side effects?

Common side effects include headache, dizziness, feeling sick, pain in tummy, rashes or skin eruptions, itching, problems with vision, and indigestion.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Voltaren® Rapid

Tablets

Active ingredient: Diclofenac Potassium

Consumer Medicine Information (CMI)

This leaflet provides important information about using Voltaren Rapid. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Voltaren Rapid.

Where to find information in this leaflet:

- 1. Why am I using Voltaren Rapid?
- 2. What should I know before I use Voltaren Rapid?
- 3. What if I am taking other medicines?
- 4. How do I use Voltaren Rapid?
- 5. What should I know while using Voltaren Rapid?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Voltaren Rapid?

Voltaren Rapid contains the active ingredient Diclofenac Potassium. It belongs to class of drugs called Nonsteroidal anti-inflammatory drugs (NSAID's). Voltaren Rapid is used to treat migraine headaches, period cramps or pain, short-term treatment (up to 1 week) of certain painful conditions associated with swelling such as back or joint pain. Voltaren Rapid helps to relieve both pain and swelling.

2. What should I know before I use Voltaren Rapid?

Warnings

Do not use Voltaren Rapid:

- if you are allergic to Diclofenac Potassium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- in children
- if you have stomach or an intestine ulcer with symptoms such as heartburn, feeling sick, vomiting, dull or burning tummy pain, bleeding from the tummy or intestine (symptoms may include blood in your stools or black stools), or any other symptoms such as severe pain in tummy, fever, feeling sick, vomiting.
- in the last three months of pregnancy.
- if you suffer from fructose intolerance (symptoms such as pain in tummy, diarrhoea) or if you have a rare genetic condition that prevents the absorption of

glucose and galactose, causing diarrhoea and other nutritional deficiency problems (glucose-galactose malabsorption)

- if you have any liver, kidney, heart diseases.
- if you are allergic to other medicines containing diclofenac (e.g. Voltfast powder), aspirin, ibuprofen or any other NSAID.

Check with your doctor if you:

- have any other medical conditions such as any heart problems, any history of heart attack, uncontrolled high blood pressure, problems with heart functions.
- take any medicines for any other condition.
- suffer from any tummy problems, swelling or ulcers in the large intestine with symptoms such as diarrhea, fever, weight loss, or any other symptoms such as fever, fatigue, pain in tummy or cramps.
- have any skin problems, skin rash or any other sign of allergic reactions.
- have asthma (disease of airways), symptoms of hay fever such as a runny nose, watery, itchy, red eyes or any long-standing infections of the respiratory tract that cause difficulty in breathing.
- have liver problems.
- suffer from any bleeding disorders or other blood problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use Voltaren Rapid in women who are trying to conceive.

If you are undergoing any treatment for infertility, check with your doctor. Your doctor will discuss with you the risks and benefits involved.

Do not use Voltaren Rapid during pregnancy. Do not use in the first 6 months of pregnancy, it may increase the risk of miscarriage. Do not use it during the last 3 months of pregnancy as it may affect your baby and may delay labour and birth. Do not use it if you are likely to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use Voltaren Rapid if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Voltaren Rapid and affect how it works.

Tell your doctor if you take any of the following medicines:

- digoxin, medicine used for treatment of heart problems
- medicines used to increase the amount of urine e.g. diuretics (Furosemide)
- medicines used to treat high blood pressure, heart problems e.g. beta-blockers (such as Propranolol), angiotensin converting enzyme (ACE) inhibitors (such as Ramipril), angiotensin II receptor antagonists (such as Valsartan)
- any other anti-inflammatory medicines, e.g. salicylates, ibuprofen or aspirin
- medicines used to prevent blood clotting e.g. warfarin
- medicines used in treatment of depression e.g. Lithium or selective serotonin-reuptake inhibitors (SSRIs)
- medicines used to treat diabetes e.g. metformin
- methotrexate, a medicine used to treat arthritis and some cancers
- medicines used in organ transplants e.g. cyclosporin and tacrolimus
- medicine used to treat urinary tract infections e.g. trimethoprim
- medicines used to treat infections e.g. quinolone antibacterials
- steroids, glucocorticoids, prednisone (medicines used to provide relief from swelling, arthritis)
- antibiotic medicine used to treat bacterial infections e.g. CYP2C9 inducers (such as rifampicin)
- phenytoin, a medicine used to treat seizures.

- medicine used to treat gout e.g. sulfinpyrazone
- voriconazole, a medicine used to treat fungal infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Voltaren Rapid.

4. How do I use Voltaren Rapid?

How much to take

- Your doctor will advise you on the appropriate dose.
- Follow the instructions provided and use Voltaren Rapid until your doctor tells you to stop.

For migraine pain

- The usual dose is 50 mg (1 tablet) daily. Take the tablet at the first signs of an attack.
- If the pain is not resolved within 2 hours, take another tablet.
- After that, you must wait at least 4 to 6 hours before taking any more Voltaren Rapid tablets.
- Do not take more than a 200 mg dose.
- Voltaren Rapid should not be used as a preventive medication for migraine.

For menstrual cramps (period pain)

- Take a 50 or 100 mg tablet as soon as the pain begins.
- This is usually followed by taking a 50 mg tablet three times daily for 3 days.

- If the pain is not resolved after 3 days' treatment, contact your doctor.
- Do not take Voltaren Rapid longer than 3 days.

For other painful conditions:

- Adults: Take a 100 to 150 mg tablet daily
- For mild symptoms and children over 14 years of age: the usual dose is 75 to 100 mg daily
- Usually, the treatment continues for a maximum of 7 days. If the pain is not resolved after 7 days, contact your doctor.

When to take Voltaren Rapid

 Take Voltaren Rapid orally as prescribed by your doctor.

How to take Voltaren Rapid

- Swallow the whole tablet with liquid, preferably before meals.
- If it upsets your stomach, you can take it with food or immediately after food.
- Do not divide or chew it.

If you forget to use Voltaren Rapid

Voltaren Rapid should be used as prescribed by your doctor. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Voltaren Rapid

If you think that you have used too much Voltaren Rapid, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Voltaren Rapid?

Things you should do

Tell your doctor if you take any medicines for any medical condition.

Call your doctor straight away if you:

- notice any symptoms such as chest pain, shortness of breath, weakness, slurring of speech
- become pregnant or intend to become pregnant or if you are breastfeeding
- notice any symptoms like feeling sick, tiredness, itching, yellowing of your skin or eyes, pain in right upper part of tummy, fever, chills
- have heart problems, tummy issues, breathing problems
- have diabetes
- suffer from any infections.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Voltaren Rapid.

Things you should not do

- Do not use Voltaren Rapid in children.
- Do not give Voltaren Rapid to anyone else, even if they seem to have the same condition as you.

Laboratory tests:

• Your doctor may do a routine blood checkup during treatment with Voltaren Rapid.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Voltaren Rapid affects you.

Voltaren Rapid may cause vision problems, dizziness, spinning sensation (vertigo), sleepiness or other central nervous system problems in some people.

If you have the above symptoms, do not drive a vehicle or operate machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

• Store below 30°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
Less serious side effects General problems: • Headache • Dizziness • Difficulty sleeping • Having nightmares • Irritability • Rashes or skin eruptions • Sleepiness • Anxiety • Spinning sensation (vertigo) • Severe headache, dizziness, or vision	What to do Speak to your doctor if you have any of these less serious side effects and they worry you.
problems Loss of hair Itching 	

Less serious side effects

Voltaren® Rapid

Less serious side effects	What to do
 Increased sensitivity of the skin to sun, symptoms such as redness, itching, swelling, blisters which may occur more quickly than normal Swelling Tummy problems: Feeling sick Vomiting Diarrhoea Indigestion Pain in tummy Excessive gas in the tummy or intestine 	
 Loss of appetite Eye and Ear problems: 	
 Vision problems Blurred vision Double vision Buzzing, hissing, whistling, ringing or other persistent noise in the ear(s) 	

Serious side effects

Serious side effects	What to do
 General problems: Symptoms of an allergic reaction which may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
 Tummy problems: Heartburn, feeling sick, vomiting, dull or burning tummy pain, feeling of fullness Dark urine, feeling tired, yellowing of your skin or eyes, light-coloured stools Blood in your stools or black stools Severe pain in tummy, fever, feeling sick, vomiting. Heart problems: 	

Serious side effects	What to do
 Fast or irregular heart beat 	
 Chest pain 	
 Chest pain which may spread to the neck and shoulders (heart attack) 	

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Voltaren Rapid contains

Active ingredient (main ingredient)	Diclofenac Potassium
Other ingredients (inactive ingredients)	Silica colloidal anhydrous, calcium phosphate, magnesium stearate, starch maize, povidone, sodium starch glycollate, cellulose microcrystalline, iron oxide red (CI No. 77491), macrogol 8000, sucrose, talc purified and titanium dioxide.
Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

What Voltaren Rapid looks like

Voltaren Rapid tablets are reddish-brown, round, biconvex sugar-coated tablets, which come in PVC/ Aluminium foil blister packs containing 20 coated tablets of 50 mg diclofenac potassium.

Australian registration number:

50 mg tablet AUST R 42943

Who distributes Voltaren Rapid

Voltaren Rapid is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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