

# Voltaren® Tablets & Suppositories

Diclofenac sodium

## Consumer Medicine Information (CMI) summary

The [full CMI](#) 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?

Voltaren contains the active ingredient Diclofenac sodium. Voltaren tablets are used to treat certain joint conditions such as osteoarthritis, Rheumatoid arthritis, period cramps or pain, other painful conditions associated with swelling such as back pain, muscle sprains. Voltaren Suppositories are used to relieve pain after surgery in children and are also used to treat certain joint conditions such as osteoarthritis, Rheumatoid arthritis.

For more information, see Section [1. Why am I using Voltaren?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to Voltaren 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 [2. What should I know before I use Voltaren?](#) in the full CMI.

### 3. What if I am taking other medicines?

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

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Voltaren?

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

More instructions can be found in Section [4. How do I use Voltaren?](#) in the full CMI.

### 5. What should I know while using Voltaren?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Voltaren.</li><li>• Tell your doctor immediately if you become pregnant or intend to become pregnant or if you are breastfeeding.</li><li>• Tell your doctor immediately if you or your child is going to have any surgery.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Voltaren in children less than 12 months of age.</li><li>• Do not give Voltaren to anyone else, even if they seem to have the same condition as you.</li><li>• Do not use Voltaren suppositories for more than 3 days in children</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Voltaren may cause vision problems, dizziness, spinning sensation (vertigo), sleepiness or other central nervous system problems in some people.</li><li>• If you have the above symptoms, do not drive a vehicle or operate machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Tablets: store below 30°C.</li><li>• Suppositories: store below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Voltaren?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include headache, feeling sick, vomiting, dizziness, indigestion, loss of appetite, problems with vision.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Voltaren®

Tablets & Suppositories

**Active ingredient:** *Diclofenac sodium*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Voltaren. **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.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Voltaren?

**Voltaren contains the active ingredient Diclofenac sodium.** It belongs to class of drugs called Nonsteroidal anti-inflammatory drugs (NSAID's). It helps to relieve both pain and swelling.

**Voltaren Tablets are used to treat:**

- certain conditions such as osteoarthritis, joint condition having symptoms such as joint pain, swelling, joint stiffness. Rheumatoid arthritis, joint disease characterized by joint swelling, redness and warmth, joint pain, fever
- other painful conditions where swelling is a problem such as back pain, muscle sprains.
- period cramps

**Voltaren Suppositories are used to:**

- treat certain joint diseases such as Osteoarthritis and Rheumatoid arthritis.
- relieve pain after surgery in children.

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

### Warnings

**Do not use Voltaren Tablets:**

- If you are allergic to Diclofenac sodium, 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.
- If you have stomach or intestine ulcer, symptoms include heartburn, feeling sick, vomiting, dull or burning stomach pain, bleeding from the stomach or intestine (symptoms such as blood in your stools or

black stools), or any other symptoms such as severe pain in tummy, fever, feeling sick, vomiting.

- In last three months of pregnancy.
- If you have liver or kidney problems.
- If you suffer from any heart diseases or if you have a history of heart bypass surgery.
- In children less than 12 months of age.
- If you are allergic to other medicines containing diclofenac (e.g. Voltfast powder), aspirin or any other NSAIDs (allergic reaction symptoms may include hives, difficulty breathing, swelling of the face, lips, tongue or other parts of the body).
- If you have ever developed a skin rash or skin peeling, blistering and/or mouth sore after taking Voltaren or other pain medications.

**Do not use Voltaren Suppositories if:**

- You suffer from Proctitis (sore back passage, sometimes with bleeding and discharge)

**Check with your doctor if you:**

- have heart problems, any history of heart attack, uncontrolled high blood pressure, problems with heart functions
- suffer from Leg pain while walking, muscle pain or cramps in the arms or legs or calf.
- have high levels of cholesterol in your blood.
- suffer from diabetes
- smoke or if you have history of smoking.
- have any stomach problems
- Suffer from loose and urgent bowel movements, blood in stool, stomach pain, feeling sick ulcerative colitis, or stomach cramps, constipation, weight loss.
- have bleeding disorders or other blood disorders
- have any skin problems, skin rash or any other sign of allergic reactions.
- have asthma (disease of airways), symptoms of hay fever such as runny nose, watery, itchy, red eyes or any long-standing infections of the respiratory tract that cause difficulty in breathing.
- suffer from symptoms such as feeling sick, vomiting, pain in stomach, diarrhea or if you have a rare genetic condition called glucose-galactose malabsorption, symptoms include severe diarrhea, which can cause dehydration and weight loss
- have symptoms such as severe abdominal pain, diarrhea or constipation, tiredness.

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 [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

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

Do not use Voltaren 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 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, may cause complications during pregnancy or 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 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 and affect how it works.**

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

- digoxin, drug used for treatment of heart problems.
- drugs 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)
- drugs 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 drug used to treat arthritis and some cancers
- medicines used in organ transplants e.g. cyclosporin and tacrolimus
- any other anti-inflammatory medicines, e.g. salicylates, ibuprofen or aspirin
- medicine used to treat urinary tract infections e.g. trimethoprim
- drugs 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 drug 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.**

### 4. How do I use Voltaren?

#### How much to take

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

#### For arthritis or other painful conditions

- Initial dose is 75 to 150 mg daily.
- After the early stages of treatment, it is usually possible to reduce the dose to 75mg to 100mg each day.
- A maximum daily dose of 150 mg should not be exceeded.

#### For menstrual cramps

- The usual starting dose of Voltaren tablets is 50mg to 100mg each day, usually taken during each period as soon as cramps begin and continued for a few days until the pain goes away.
- If necessary, the dose can be raised over several menstrual periods to a maximum of 200mg each day.

#### For post-operative pain in children

- Your doctor will advise you the appropriate dose of Voltaren suppositories for your child depending on your child's weight.
- Ask your doctor or pharmacist if you do not understand the dose.
- Voltaren 100 mg suppositories are not suitable for children and adolescents.
- Voltaren suppositories should not be used in children under 12 months of age.

#### When to take Voltaren

##### Voltaren Tablets:

- Take Voltaren tablets before meals or on an empty stomach. If they upset your stomach, you can take them with food or immediately after food.

##### Voltaren suppositories:

- Use the suppositories at bedtime to relieve pain during the night and early morning stiffness; or to relieve pain after an operation.

#### How to take Voltaren

##### Voltaren tablets:

- Swallow the tablets whole with liquid, preferably before meals. Do not divide or chew the tablets.

##### How to use Voltaren suppositories:

- If possible, go to the toilet and empty your bowels before using the suppository.
- Then follow the below steps:
- Clean your hands thoroughly with soap and water.

- If the suppository feels soft, cool it before removing the wrapper by placing it in the fridge or holding it under cold water for a few minutes.
- Put on a disposable glove, if desired.
- Remove the entire wrapper from the suppository.
- Briefly dip the suppository in cool water to moisten.
- Lie on your side and raise your knees to your chest.
- Push the suppository, blunt end first, gently into your rectum (back passage). Do not break the suppository.
- Remain lying down for a few minutes so that the suppository dissolves.
- Wash your hands again thoroughly.
- Avoid emptying your bowels for at least one hour after using the suppository.
- If you are not sure how to use a suppository, ask your pharmacist or doctor.
- Do not take suppositories by mouth.

**Do not use Voltaren suppositories for more than 3 days in children.**

### **If you forget to take/use Voltaren**

Voltaren 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**

If you think that you have used too much Voltaren, 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?**

### **Things you should do**

- Tell your doctor immediately if you or your child is going to have any surgery.

### **Call your doctor straight away if you:**

- notice any symptoms such as chest pain, shortness of breath, weakness, slurring of speech
- develop any signs of allergic reaction.
- become pregnant or intend to become pregnant or if you are breastfeeding.

- have symptoms like feeling sick, tiredness, lethargy, itching, yellowing of your skin or eyes pain in right upper part of stomach.
- suffer from any infections, symptoms such as fever, chills, sore throat
- have heart diseases, breathing problems.

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

### **Things you should not do**

- Do not give Voltaren to anyone else, even if they seem to have the same condition as you.
- Do not use Voltaren to treat any other complaints unless your doctor tells you to.
- Do not use Voltaren suppositories for more than 3 days in children.

### **laboratory tests**

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

### **Driving or using machines**

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

Voltaren 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**

- Tablets: store below 30°C.
- Suppositories: store below 25°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.**

### **When to discard your medicine (as relevant)**

**[Include any specific information about discarding the medicine e.g. 28 day expiry from date of first use].**

### **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

Less serious side effects	What to do
<b>General problems:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Dizziness.</li><li>• Spinning sensation</li><li>• Problems with vision</li><li>• Blurred vision</li><li>• Inability to sleep</li><li>• Buzzing, hissing, whistling, ringing or other persistent noise in the ear(s)</li><li>• Double vision</li><li>• Nightmare</li><li>• Severe headache, dizziness, vision problems</li><li>• Loss of hair</li></ul> <b>Stomach problems:</b> <ul style="list-style-type: none"><li>• Feeling sick</li><li>• Vomiting</li><li>• Diarrhoea</li><li>• Indigestion</li><li>• Pain in stomach</li><li>• Excessive gas in stomach or intestine</li><li>• Loss of appetite</li><li>• Constipation</li><li>• Worsening of haemorrhoids (piles)</li></ul> <b>Skin problems:</b> <ul style="list-style-type: none"><li>• Rashes</li><li>• Application site irritation</li><li>• Itching</li><li>• Swelling</li></ul> <b>Abnormal blood results:</b> <ul style="list-style-type: none"><li>• Weakness, shortness of breath, dizziness or lightheadedness, pale skin, headache</li><li>• Stomach pain, yellowing of skin or eyes, dark urine, tiredness.</li><li>• Easy bruising, excessive bleeding after minor injuries, tiredness.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>General problems:</b> <ul style="list-style-type: none"><li>• A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching. Darkening of the skin in affected areas, which might persist after healing, may also occur.</li></ul> <b>Heart problems:</b> <ul style="list-style-type: none"><li>• Fast or irregular heart beats</li><li>• Chest pain</li><li>• Chest pain which may spread to the neck and shoulders (heart attack)</li></ul> <b>Stomach problems:</b> <ul style="list-style-type: none"><li>• Heartburn, feeling sick, vomiting, dull or burning stomach pain</li><li>• Blood in your stools or black stools</li><li>• Severe pain in tummy, fever, feeling sick, vomiting.</li></ul>	<b>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.</b>

**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 [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 contains

<b>Active ingredient (main ingredient)</b>	Voltaren Tablets are enteric coated and contain either 25 mg or 50 mg of diclofenac sodium.  Voltaren Suppositories: contain either 12.5 mg, 25 mg, 50 mg or 100 mg diclofenac sodium
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<b>Other ingredients (inactive ingredients)</b>	Tablets: colloidal anhydrous silica, microcrystalline cellulose, lactose monohydrate, magnesium stearate, maize starch, povidone, hypromellose, iron oxide yellow, titanium dioxide, sodium starch glycolate, purified talc, macrogol 8000, PEG-40 hydrogenated castor oil, acrylates copolymer, iron oxide red (50 mg tablet only), Wacker Silicone Fluid Emulsion E 2 (proprietary ingredient) Suppositories: triglyceride base.
<b>Potential allergens</b>	Tablets: lactose monohydrate

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

### **What Voltaren looks like**

**Voltaren Tablets are Enteric coated tablets. They are available in the following strengths:**

25 mg: They are yellow, round, slightly biconvex tablets with bevelled edges. Debossed with BZ on one side and CG on reverse side'. They come in PVC/PE/PVDC/Al blister packs of 20 (not marketed) and 50; HDPE bottle packs of 20 (not marketed) and 50.

50 mg: They are light brown, round, slightly convex, coated tablets. Imprinted with CG on one side and GT on the other'. They come in PVC/PE/PVDC/Al or PVC/Al blister packs of 10 (samples), and 50; HDPE bottle packs of 16, 20, and 50.

**Voltaren Suppositories are available in the following strengths:**

12.5 mg, 25 mg and 50 mg: They are white to yellowish torpedo-shaped with smooth surfaces'. They come in PVC/PE blister packs of 10.

100 mg: They are yellowish white "torpedo shaped" suppository, rounded one end, flat at other, being 30 mm long 12 mm diameter at widest part tapering to 9 mm small end'. They come in PVC/PE blister packs of 5 (not currently marketed), 20.

### **Australian Registration Numbers:**

25mg tablet blister AUST R 166496

50mg tablet blister AUST R 66880

12.5mg suppository AUST R 96797

25mg suppository AUST R 96810

50mg suppository AUST R 96811

100mg suppository AUST R 37582

### **Who distributes Voltaren**

Voltaren is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160