

# VOLTAREN®

## 75mg/3ml solution for injection

### diclofenac sodium

#### What is in this leaflet

This leaflet answers some common questions about Voltaren Solution for Injection.

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 having it against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What Voltaren Solution for injection is used for

Voltaren relieves pain and reduces inflammation (swelling and redness). It has no effect on the causes of inflammation.

Injections of Voltaren into a muscle are used to treat the following conditions:

- Pain due to gallstones or kidney stones.
- Severe migraine attacks

Infusions of Voltaren into a vein are used to:

- treat or prevent pain following surgery

Voltaren 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 Voltaren for another purpose.

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

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

#### Before you have Voltaren Solution for Injection

##### **When you must not have it**

**Do not have Voltaren Solution for Injection if you have an allergy to:**

- diclofenac (the active ingredient in Voltaren) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac (eg. Voltaren Emulgel)
- 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 having 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 have Voltaren Solution for Injection, these symptoms may be severe.**

**Do not have Voltaren Solution for Injection if at the present time you have an ulcer (gastric or duodenal) or bleeding from the stomach or bowel.**

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

**Do not have Voltaren Solution for Injection 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 have Voltaren Solution for Injection after the expiry date (EXP) printed on the pack.**

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

**Do not have Voltaren Solution for Injection if the packaging is torn or shows signs of tampering.**

**Voltaren ampoules are not recommended for use in children.**

**If you are not sure whether you should start having Voltaren Solution for Injection, contact your doctor.**

##### **Before you start to have 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)

**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 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.
- 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.
- kidney disease
- liver disease
- a tendency to bleed or other blood problems such as anaemia
- asthma
- If you recently had or you are going to have a surgery of the stomach or intestinal tract.

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

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

If you have Voltaren Solution for Injection 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, Voltaren is not recommended for use during pregnancy or breast-feeding. Use of NSAIDs may increase the risk of miscarriage particularly when taken close to the time of conception. As with other NSAIDs, use of this medicine during the third trimester of pregnancy is contraindicated due to the possibility of uterus not contracting properly, fetal kidney complications and other fetal complications. Your doctor will discuss with you the benefits and risks of having it.

Injection site reactions have been reported after intramuscular administration (technique used to deliver a medication deep into the muscles) of Voltaren, including injection site pain, redness, swelling/hard lump, ulcer, sometimes with bruise or collection of pus, and destruction of skin and tissue underneath the skin (particularly after incorrect administration in the fatty tissue) - a phenomenon known as Nicolau syndrome.

***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 (such as metformin)
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin, tacrolimus, 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)
- sulfapyrazone (a medicine used to treat gout)
- phenytoin (a medicine used to treat seizures).
- Rifampicin (an antibiotic medicine used to treat bacterial infections).
- Your doctor or pharmacist has more information on medicines to be careful with or avoid while having Voltaren.

**If you have not told your doctor about any of these things, tell them before you have Voltaren Solution for Injection.**

**How Voltaren Solution for Injection is given**

**Intramuscular injection**

Your doctor or nurse will draw the solution from the ampoule into a syringe and inject the solution deep into your buttock muscle.

**Intravenous injection**

Your doctor or nurse will dilute the solution with at least 100ml of a modified solution of common salt or glucose and slowly infuse into a vein. It must not be injected too quickly into the vein.

***How much is given***

Your doctor will assess your situation and the lowest effective dose for the shortest possible duration will be prescribed. The usual dosage is one ampoule a day given for two days at the most, in some cases, two ampoules may be given a day. If further treatment with Voltaren is needed, this can be given in the form of Voltaren tablets or suppositories.

## **How long is Voltaren Solution for Injection given**

Voltaren ampoules should not be given for more than 2 days. If necessary, treatment can be continued with Voltaren tablets or suppositories.

## **If you are given too much (Overdose)**

Immediately tell your doctor or telephone the National Poisons Information Centre, Dunedin (phone 0800 POISON or 0800 764 766), or go the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have had too much Voltaren Solution for Injection. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

## **While you are given Voltaren Solution for Injection**

### **Things you must do**

**If you are or become pregnant while having Voltaren Solution for Injection, tell your doctor immediately.**

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

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are having Voltaren Solution for Injection.**

**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 you to have 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 Voltaren, especially in case you are treated for more than 4 weeks.

**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.**

**If you are going to have surgery, make sure the surgeon and anaesthetist know that you are having Voltaren Solution for Injection.**

NSAID medicines can slow down blood clotting.

**If you get an infection while having Voltaren Solution for Injection, 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 having Voltaren Solution for Injection.**

### **Things you must not do**

**Do not take any other medicines used to treat arthritis while you are having Voltaren Solution for Injection 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 have these medicines together with Voltaren Solution for Injection, they may cause unwanted effects.

If you need to have something for headache or fever, it is usually okay to have paracetamol. If you are not sure, ask your doctor.

**Do not use Voltaren Solution for Injection 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 Voltaren Solution for Injection affects you.**

As with other NSAID medicines, Voltaren Solution for Injection 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 having Voltaren Solution for Injection.**

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 having 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
- injection site reaction
- skin rash, fever, swollen face or neck

**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
- signs of 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
- 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

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

**If any of the following happen, stop having Voltaren Solution for Injection 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
- stiff neck (signs of viral meningitis)
- raised blood pressure

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

**Side effect with frequency not known**

Nicolau syndrome – seen with immediate strong painful sensation at the injection site followed by redness, swelling, lump, may be with blockade of blood vessels resulting in destruction of skin and tissue underneath the skin).

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

Some people may get other side effects of Voltaren Solution for Injection.

## **After using Voltaren Solution for Injection**

### **Storage**

**If you have to store Voltaren Solution for Injection at home:**

- Keep your medicine in the original container until it is time to have it.
- Store the container in a cool dry place below 30°C.

- Do not store Voltaren Solution for Injection 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 stops your treatment with Voltaren Solution for Injection 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***

Voltaren Solution for Injection comes in a 3ml colourless glass ampoules. Each pack contains 5 ampoules.

### ***Ingredients***

Voltaren ampoules contain 75mg of diclofenac sodium as the active ingredient. They also contain the following ingredients:

- mannitol
- sodium metabisulphite
- benzyl alcohol
- propylene glycol
- water for injection
- sodium hydroxide
- nitrogen pure.

### ***Sponsor***

Voltaren Solution for Injection is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand

Telephone 0800 354 335

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