

Package leaflet: Information for the patient

VOLTAREN[®] 75 mg/3 mL Solution for injection

diclofenac sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep the leaflet. You may need to read it again.

If you have any further questions ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Voltaren is and what it is used for
- What you need to know before you take Voltaren
- How to take Voltaren
- Possible side effects
- How to store Voltaren
- Contents of the pack and other information

1 What Voltaren is and what it is used for

Voltaren solution for injection contains the active ingredient diclofenac sodium. Voltaren belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs). NSAIDs reduce pain and inflammation, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

The intramuscular injection is used to reduce fever and treat a number of conditions including:

- Flare-ups of joint or back pain, frozen shoulder, tennis elbow, and other types of rheumatism.
- Attacks of gout
- Pain caused by gallstones or kidney stones.
- Pain and swelling following surgery and injuries
- Severe migraine attacks.

Voltaren can either be given as an injection into the muscle, or as a slow infusion into a vein. The intravenous infusion is used in hospitals to prevent or treat pain following surgery.

Voltaren is not suitable for children.

Monitoring during your treatment with Voltaren

If you have established heart disease or significant risks for heart disease, 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 you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Voltaren needs to be discontinued or if the dose needs to be changed.

2. What you need to know before you take Voltaren

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Voltaren, as Voltaren can sometimes worsen wound healing in your gut after surgery.

Do not take Voltaren

- If you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID or to any of the other ingredients of Voltaren Ampoules (including sodium metabisulphite). (These are listed at the end of this leaflet.) Signs of a hypersensitivity reaction may include asthma, runny nose, skin rash, swelling of the face and mouth, lips, tongue, throat and/or extremities (signs of angioedema) breathing problems, chest pain or any other type of reaction. If you think you may be allergic, ask your doctor for advice.
- If you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, perforation or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- If you had stomach or bowel problems after you have taken other NSAIDs
- If you have kidney or liver failure.
- If you are more than six months pregnant.
- If you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- If you have or have had problems with your blood circulation (peripheral arterial disease)
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Voltaren

- If you suffer from any bowel disorders including ulcerative colitis or Crohn's disease
- If you have kidney or liver problems, or you are elderly
- If you suffer from any blood or bleeding disorder?
- If you have a condition called porphyria
- If you have ever had asthma or hay fever (seasonal allergic rhinitis)
- If you could be suffering from dehydration (e.g. by sickness, diarrhea, before or after major surgery)
- If you have you suffered any heavy loss of blood recently
- If you have swollen feet
- If you smoke, have diabetes, have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides you must not increase the dose above 100mg per day if you are treated for more than 4 weeks.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltaren solution for injection or other pain medications.

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 think you may be allergic, ask your doctor for advice.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Children and adolescents

Voltaren Ampoules should not be used in premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and children up to 3 years old. Solution for injection must not be used in children and adolescents (below 18 years of age).

Other medicines and Voltaren

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine

- Medicines (such as metformin) to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets).
- Lithium (used to treat some mental problem).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin, Tacrolimus (used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibiotics (for infections)
- Any other NSAID, for example aspirin or ibuprofen
- Cardiac glycosides (for example digoxin), used to treat heart problems).
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)

- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol and cholestyramine (medicines used to lower cholesterol levels).
- Rifampicin (an antibiotic medicine used to treat bacterial infections).

Pregnancy, breast-feeding and fertility

- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take a Voltaren Injection during the last 3 months of pregnancy as it may affect the baby's circulation. It could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Voltaren during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. From 20 weeks of pregnancy, Voltaren can cause kidney problems in your unborn baby, if taken for more than a few days, which can lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios). If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
- Are you trying for a baby? Having Voltaren Injections may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.
- Are you breast-feeding? Since the drug can pass into the breast milk in small amounts, it is advisable not to take medication during breast feeding.
Ask your doctor or pharmacist for advice before taking any medicines.

Your doctor will discuss with you the potential risk of taking Voltaren during pregnancy or breast-feeding.

Other special warnings

- You should take the lowest dose of Voltaren for the shortest possible time, particularly if you are underweight or elderly.
- There is an increased risk of heart attack or stroke when you are taking any medicine like Voltaren. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for. Whilst you are taking these medicines your doctor may want to give you a check-up from time to time. Blood tests are recommended when taking treatment for a long time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms since you may need to stop treatment.
- Because it is an anti-inflammatory medicine, Voltaren may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Voltaren.
- Voltaren Ampoules contain the preservative, sodium metabisulphite. This can sometimes cause allergic reactions and breathing difficulties.

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.

- This medicine contains less than 1 mmol sodium (23 mg) in 3 milliliter, that is to say essentially “sodium-free”.
- This medicine contains 120 mg benzyl alcohol in 3 milliliter which is equivalent to 40 mg/ml. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (metabolic acidosis).

- This medicine contains 600 mg of propylene glycol (E 1520) in 3 milliliter which is equivalent to 200 mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.
- Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
- The sodium metabisulphite present in solution may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take Voltaren

Always take this medicine exactly as your doctor has told you. You will either be given an intravenous infusion (a drip into a vein) or an intramuscular injection (an injection into a muscle). The intramuscular injection is usually injection into the buttocks.

The recommended dose is:

Adults

The content of one or two ampoules (75 to 150 mg) each day for one or two days.

Elderly

Your doctor may give you a dose that is lower than the usual adult dose if you are elderly.

Use in children and adolescents

Not suitable for children. Solution for injection must not be used in children and adolescents (below 18 years of age).

Injection into a muscle: The solution is drawn from the ampoule into a syringe and injected deep into your buttock muscle.

Infusion into a vein: The solution is diluted with at least 100 mL of a modified solution of common salt or glucose and slowly infused into a vein. It must not be injected quickly into the vein.

A doctor, nurse or pharmacist will prepare the injection for you.

If you have had an operation and are in hospital, the ampoule contents may be diluted and put into a drip bag before being given to you. A nurse or doctor will usually then give you the injection or infusion. You would not usually have to give the injection to yourself.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

If you take more Voltaren than you should

If you think you have been given too much Voltaren tell your doctor or nurse straight away.

4 Possible side effects

As with all medicines, patients taking Voltaren can experience side effects, although not everybody gets them.

Stop using Voltaren Ampoules and tell your doctor straight away if you notice:

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Voltaren Ampoules and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).

Some side effects could be serious

These uncommon side effects may affect between 1 and 10 in every 1000 patients, especially when taking a high daily dose (150mg) for a long period of time

- 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).

These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients

- Spontaneous bleeding or bruising (signs of thrombocytopenia).
- High fever, frequent infections, persistent sore throat (signs of agranulocytosis).
- Difficulty of breathing or swallowing, rash, itching, hives, dizziness (signs of hypersensitivity, anaphylactic and anaphylactoid reactions).
- Swelling mainly of the face and throat (signs of angioedema).
- Disturbing thoughts or moods (signs of psychotic disorders).
- Impaired memory (signs of memory impairment).
- Seizures (signs of convulsions).
- Anxiety.
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of limbs or face (signs of cerebrovascular accident or stroke).

- Difficulty of hearing (signs of impaired hearing).
- Headache, dizziness (signs of high blood pressure, hypertension).
- Rash, purplish-red spots, fever, itching (signs of vasculitis).
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or Pneumonitis if fever).
- Vomiting of blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal hemorrhage).
- Bloody diarrhea (signs of hemorrhagic diarrhea).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer, bleeding or perforation).
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, ischaemic colitis and exacerbation of ulcerative colitis or Crohn's disease).
- Severe upper stomach pain (signs of pancreatitis).
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure).
- Flu-like symptoms, feeling tired, muscles aches, increased liver enzymes in blood test results (signs of liver disorders including fulminant hepatitis, hepatic necrosis, hepatic failure).
- Blister (signs of bullous dermatitis).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling (signs of erythema multiforme or if fever signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Skin rash with flaking or peeling (signs of exfoliative dermatitis).
- Increased sensitivity of the skin to sun (signs of photosensitivity reaction).
- Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).
- Swelling, feeling weak, or abnormal urination (signs of acute renal failure).
- Excess of protein in the urine (signs of proteinuria).
- Swollen face or abdomen, high blood pressure (signs of nephrotic syndrome).
- Higher or lower urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis).
- Severely decreased urine output (signs of renal papillary necrosis).
- Generalized swelling (signs of edema).
- Coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome).

If you experience any of these, **tell your doctor straight away.**

Some side effects are common

These side effects may affect between 1 and 10 in every 100 patients

Headache, dizziness, vertigo, nausea, vomiting, diarrhea, indigestion (signs of dyspepsia), abdominal pain, flatulence, loss of appetite (signs of decreased appetite), abnormal liver function test results (e.g. level of transaminases increased), skin rash, injection site reaction, injection site pain, injection site induration.

Some side effects are rare

These side effects may affect between 1 and 10 in every 10,000 patients

Drowsiness (signs of somnolence), stomach pain (signs of gastritis), liver disorder, itchy rash (signs of urticaria), injection site necrosis.

Some side effects are very rare

These side effects may affect less than 1 in 10,000 patients

Acute kidney injury, low level of red blood cells (anemia), low level of white blood cells (leukopenia), disorientation, depression, difficulty sleeping (signs of insomnia), nightmares, irritability, tingling or numbness of the hands or feet (signs of paresthesia), trembling (signs of tremor), taste disorders (signs of dysgeusia), vision disorders* (signs of visual impairment, blurred vision, diplopia), noises in ears (signs of tinnitus), constipation, mouth sores (signs of stomatitis), swollen, red and sore tongue (signs of glossitis), disorder of the tube that carries food from the throat to the stomach (signs of esophageal disorder), upper abdomen cramp specially after eating (signs of intestinal diaphragm disease), palpitations, chest pain, itchy, red and burning rash (signs of eczema), skin reddening (signs of erythema), hair loss (signs of alopecia), itching (signs of pruritus), blood in urine (signs of hematuria), injection site abscess.

* **Vision disorders:** If symptoms of vision disorders occur during treatment with Voltaren, contact your doctor as an eye examination may be considered to exclude other causes.

not known (frequency cannot be estimated from the available data)

- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

Some side effects are of an unknown frequency

Tissue damage at injection site.

Nicolau syndrome – presents with immediate strong painful sensation at the injection site followed by redness, swelling/lump, ulcer, sometimes with bruise or collection of pus and blockage of blood vessels resulting in destruction of skin and tissue underneath the skin.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Do not be alarmed by this list - most people have an injection of Voltaren without any problems.

If you take Voltaren 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltaren

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is printed on the outside of the pack.

Store below 30°C. Protect from light and heat.

6. Contents of the pack and other

information What Voltaren contain

The glass ampoules contain 75mg of the active ingredient, diclofenac sodium, in solution.

The ampoules also contain mannitol, sodium metabisulphite (E 223), benzyl alcohol, propylene glycol, water for injection, sodium hydroxide and nitrogen pure.

Contents of the pack

Voltaren Ampoules come in packs of 5 or 10.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder

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If you would like more information please contact the local representative of the Marketing Authorisation Holder at Novartis Pharma Services Inc., P.O. Box 4, Marsa MRS 1000, Malta. Tel: +356 21222872

The following information is intended for healthcare professionals only:

Dosage and Administration

Adults:

Voltaren ampoules (given im or iv) should not be given for more than two days; if necessary, treatment can be continued with Voltaren Tablets or Suppositories.

Intramuscular injection: Appropriate injection technique and length of the needle (considering the thickness of the patient's gluteal fat) should be used to avoid inadvertent subcutaneous administration of Voltaren injection. The following directions for intramuscular injection must be adhered to in order to avoid damage to a nerve or other tissue at the injection site.

One ampoule once (or in severe cases twice) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required it is advised that the alternative buttock be used for the second injection, and the injections are separated by an interval of a few hours. Alternatively, one ampoule of 75mg can be combined with other dosage forms of Voltaren (tablets or suppositories) up to the maximum daily dosage of 150mg.

Renal colic: One 75mg ampoule intramuscularly. A further ampoule may be administered after 30 minutes if necessary. The recommended maximum daily dose of Voltaren is 150mg.

Recommended injection procedure

1. The patient may lie down or stand (holding a stable piece of furniture for support) whichever is most comfortable.
2. The buttocks should be exposed and inspected to find the most suitable injection site. Avoid scars and lumps and choose the buttock which is free from any problems. If more than one injection needs to be given the other buttock should be used.
3. The injection site should be thoroughly disinfected e.g. with isopropyl alcohol and allowed to dry before injecting the solution.
4. Give the deep intramuscular injection high into upper outer quadrant (for boundary definitions see diagram) of the buttock taking particular care to avoid the sciatic nerve (see diagram) and blood vessels (see point 5 below). Avoid injecting into an area where resistance is felt.

N.B. In obese patients avoid deposition of the drug into the subcutaneous fatty tissue. In small thin patients with little muscle bulk, be especially aware of the sciatic nerve which may be quite superficial.

5. Before injection and after needle insertion, pull back the syringe plunger to check the needle has not entered a vessel. If blood is drawn, withdraw the needle to another site and check again.
6. The injection should be given slowly to minimise local tissue damage.

7. If the patient complains of severe pain or pronounced discomfort stop the injection immediately. Retry at another site. A dull aching pain may be experienced after normal injection.
8. Advise the patient to remain reasonably mobile for one to two hours after the injection, whenever possible.

Intravenous Infusion: Immediately before initiating an intravenous infusion, Voltaren must be diluted with 100-500 ml of either sodium chloride solution (0.9%) or glucose solution (5%). Both solutions should be buffered with sodium bicarbonate solution (0.5ml 8.4% or 1ml 4.2%). Only clear solutions should be used.

Intravenous infusions should be freshly made up and used immediately. Once prepared, the infusion should not be stored.

Voltaren must not be given as an intravenous bolus injection.

Two alternative regimens are recommended:

For the *treatment* of moderate to severe post-operative pain, 75 mg should be infused continuously over a period of 30 minutes to 2 hours. If necessary, treatment may be repeated after 4-6 hours, not exceeding 150 mg within any period of 24 hours.

For the *prevention* of post-operative pain, a loading dose of 25 mg-50 mg should be infused after surgery over 15 minutes to 1 hour, followed by a continuous infusion of approx. 5mg per hour up to a maximum daily dosage of 150mg.

Children:

Voltaren ampoules are not recommended for use in children.

Elderly: Although the pharmacokinetics of Voltaren are not impaired to any clinically relevant extent in elderly patients, non-steroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also Precautions) and the patient should be monitored for GI bleeding for 4 weeks following initiation of NSAID therapy.

The recommended maximum daily dose of Voltaren is 150mg.

Incompatibilities

The ampoules used im or iv as an infusion should not be mixed with other injection solutions.

Shelf life

Two years.

Special precautions for storage

Protect from light and heat (store below 30°C).

Medicines should be kept out of the reach of children.

The infusion solution should not be used if crystals or precipitates are observed.

Nature and contents of container

The glass ampoules (Ph.Eur. Type I) contain colourless to faintly yellow liquid and come in packs of 5 or 10.