

Package Leaflet: Information for the user

VOLTAROL® Ampoules 75mg/3ml solution for injection (diclofenac sodium)

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

- Keep this 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 onto 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.
- This medicine will be referred to as Voltarol in this leaflet.

What is in this leaflet

1. What Voltarol is and what it is used for
2. What you need to know before you have Voltarol
3. How to have Voltarol
4. Possible side effects
5. How to store Voltarol
6. Contents of the pack and other information

1. What Voltarol is and what it is used for

Diclofenac sodium, the active ingredient in Voltarol is one of a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs). NSAIDs reduce pain and inflammation. They have no effect on the causes of inflammation.

Voltarol is used to treat a number of painful conditions including:

- “flare-ups” of joint pain
- attacks of gout
- pain caused by gallstones or kidney stones
- pain and swelling caused by an injury or after an operation.

Voltarol is given by injection into a muscle (“intramuscular” injection).

2. What you need to know before you have Voltarol

Do not have Voltarol if:

- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the gut (digestive tract). This can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black tarry stools. This may have been when you used an NSAID before
- you are in the last three months of pregnancy
- you have severe kidney or liver problems
- you have ever had an allergic reaction (such as asthma, wheezing, skin rash, face swelling, runny nose) after taking medicines to treat pain and inflammation (NSAIDs) such as aspirin or ibuprofen
- you think you may be allergic to diclofenac sodium, sodium metabisulphite, benzyl alcohol, propylene glycol or to any of the other ingredients of Voltarol (listed in Section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems,

runny nose, skin rash or any other allergic type reaction (see also Section 2 “Voltarol contains sodium metabisulphate, benzyl alcohol and propylene glycol”)

- you have heart disease (e.g. if you have had a heart attack, have angina or blockages in the arteries of your heart)
- you have cerebrovascular disease (e.g. if you have had a stroke, mini-stroke or have blockages of the arteries to the brain)
- you have peripheral arterial disease (e.g. poor circulation or blockages of the arteries to the legs and feet)
- you have severe heart failure
- you are a child under 14 years of age.

Do not have Voltarol if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before having Voltarol.

Warnings and precautions

Talk to your doctor or pharmacist before having your medicine if:

- if you have diabetes
- if you smoke
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- you have bowel problems such as ulcerative colitis or Crohn’s disease
- you have kidney or liver problems you have any blood or bleeding problems - your doctor will take regular blood tests
- you have a condition called porphyria
- you have ever had asthma, other breathing problems (such as chronic obstructive pulmonary diseases, COPD) or often get chest infections
- you have ever had hay fever or nasal polyps
- you have any allergies
- you could be dehydrated
- you have ever had stomach or bowel problems.

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before having Voltarol.

If you have significant risk factors for cardiovascular disease 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 Voltarol, you must use the lowest effective dosage for the shortest duration necessary.

Look out for serious side effects

Voltarol can cause some serious side effects. These are listed at the beginning of Section 4. You will need to look out for these while you are having Voltarol. If you get a serious side effect you need to stop taking Voltarol and talk to your doctor straight away. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Risk of heart attack or stroke with Voltarol

There is a small increased risk of heart attack or stroke when you are taking any medicine like Voltarol. The risk is higher when you are taking higher doses for a long time. Always follow the doctor’s instructions on how much to have and how long to have it for. If, at any time while taking Voltarol 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.

Signs of infection

Because it is an anti-inflammatory medicine, Voltarol 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 having Voltarol.

Tests and checks

If you have significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Voltarol.

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor the function of your liver, kidney or your blood count. Your doctor will take these blood tests into consideration to decide if Voltarol needs to be discontinued or if the dose needs to be changed.

If you are elderly or underweight

If you are elderly or underweight you may be more sensitive to the effects of Voltarol than other adults. Follow your doctor's instructions carefully. Try to have the smallest amount of Voltarol that gives you relief, for the shortest possible time. Tell your doctor straight away if you get any side effects, especially stomach problems.

Children and adolescents

This medicine is not recommended for use in children and adolescents. It must not be given to children under 14 years of age.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription or herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines to treat diabetes
- anticoagulants (blood thinning tablets like warfarin)
- diuretics (water tablets)
- lithium (used to treat some mental problems)
- methotrexate (for some inflammatory diseases and some cancers)
- ciclosporin, tacrolimus (medicines primarily used in patients who have received organ transplants) Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- quinolone antibiotics (for infections)
- voriconazole (for fungal infections)
- any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- digoxin (used to treat heart problems)
- medicines known as SSRIs used to treat depression
- oral steroids (an anti-inflammatory drug)
- phenytoin (used to treat seizures)

- medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors.
- colestipol and cholestyramine (used to treat high cholesterol). These medicines can reduce the effect of Voltarol. Take Voltarol at least 1 hour before or 4 to 6 hours after taking these medicines.

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before having Voltarol.

Fertility, pregnancy and breast-feeding

Talk to your doctor before having this medicine if you are pregnant, might become pregnant or are breast-feeding.

- Having Voltarol may make it more difficult to get pregnant. You should talk to your doctor if you are planning to become pregnant or if you have problems getting pregnant.
- Do not take Voltarol if you are in the last three months of pregnancy as it could harm your unborn child or cause problems at delivery. You should not take Voltarol during the first 6 months of pregnancy unless absolutely necessary.
- Do not breast-feed if you are having Voltarol. This is because small amounts may pass into the mother's milk.

Driving and using machines

Very occasionally people have reported that Voltarol has made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way you should not drive or use any tools or machines.

Voltarol contains sodium metabisulphate, benzyl alcohol, propylene glycol and sodium

- Voltarol contains the preservative, sodium metabisulphate. This can sometimes cause allergic reactions and breathing difficulties.
- Voltarol contains benzyl alcohol (120mg/3ml). This must not be given to premature babies or neonates. It may cause toxic or allergic reactions in infants and children up to 3 years old.
- Voltarol contains propylene glycol which may cause alcohol-like symptoms.
- Voltarol contains sodium. Take this into consideration if you are on a low-salt (sodium) diet. This product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially "sodium free"

3. How to have Voltarol

Voltarol will be given to you by a doctor or nurse.

Having this medicine

Voltarol is given by injection into a muscle ("intramuscular" injection). This is usually an injection into the buttocks.

- The doctor may also prescribe another medicine 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 medicines as well.
- If further treatment with Voltarol is needed, this can be given in the form of Voltarol tablets or suppositories.

How much to have:

Adults

The recommended dose is one or two ampoules (75 to 150 mg) each day for one or two days.

The elderly

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

Children and adolescents

This medicine is not recommended for children and adolescents. It must not be given to children under 14 years of age.

If you are given too much Voltarol

If you think you have been given too much Voltarol tell your doctor or nurse straight away. The following effects may happen: vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, hearing problems or fits. In severe overdose kidney or liver problems can happen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Voltarol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Some side effects could be serious. Stop having Voltarol and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Chest pain or tightness with shortness of breath (*may affect between 1 and 10 in every 1000 patients*)
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (*may affect between 1 and 10 in every 1000 patients*)
- Vomiting of blood, bleeding from the bowel (*may affect from less than 1 to 10 in every 10,000 patients*)
- Sudden slurred speech, facial drooping, weakness, disorientation, or speech problems (*may affect from less than 1 to 10 in every 10,000 patients*)
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (“bronchospasm”), swollen face, lips hands or fingers, hypotension (low blood pressure) and fainting (*may affect from less than 1 to 10 in every 10,000 patients*)

The following side effects have also been reported in patients taking Voltarol

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

- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (“bronchospasm”), swollen face, lips hands or fingers, hypotension (low blood pressure) and fainting
- stomach pain, indigestion, heartburn, wind, feeling sick (nausea), or being sick (vomiting)
- any sign of bleeding in your stomach or intestine, for example, when emptying your bowels, blood in vomit, or black tarry faeces
- yellowing of your skin or the whites of your eyes
- pain in your abdomen and lower back, with feeling or being sick or loss of appetite (possible signs of pancreatitis)
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance
- bruising more easily than usual
- frequent sore throats or infections
- fits, headaches together with a dislike of bright lights, fever and a stiff neck

- headache and dizziness (signs of high blood pressure, hypertension)
- serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome
- sudden severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (possible signs of stroke)

Stop having Voltarol and see a doctor straight away if you notice any of these side effects.

Other side effects

Common (may affect up to 1 in 10 people)

- stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- headache, dizziness, vertigo
- skin rash or spots
- raised levels of liver enzymes in the blood
- pain, swelling or reactions at the injection site.

Rare (may affect up to 1 in 1,000 people)

- stomach ulcers or bleeding (there have been very rarely reported cases resulting in death, particularly in the elderly)
- drowsiness, tiredness
- skin rash and itching
- fluid retention, symptoms of which include swollen ankles
- death of skin tissue at the injection site (necrosis).

Very rare (may affect up to 1 in 10,000 people)

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and loss of memory.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, taste changes, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or liver disorders, presence of blood or protein in the urine.

Effects on skin or hair:

Skin rashes which may be made worse by exposure to sunlight, hair loss, abscess at the site of the injection.

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

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House,

Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. How to store Voltarol

- Store below 30°C. Store in the original package in order to protect from light.
- Keep this medicine out of the sight and reach of children.
- Do not use Voltarol after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Voltarol Ampoules contain

- The active substance is diclofenac sodium. Each 3 ml ampoule contains 75 mg of diclofenac sodium in solution (25mg/ml).
- The other ingredients are mannitol (E421), sodium metabisulphite (E223), benzyl alcohol, propylene glycol, water for injection and sodium hydroxide.

What Voltarol Ampoules look like and contents of the pack

- Voltarol Ampoules are a clear, colourless to faintly yellow.
- Voltarol Ampoules come in packs of 10.

Marketing Authorisation Holder and Manufacturer

Novartis Pharmaceuticals UK Limited, Frimley Business Park,
Frimley, Camberley, Surrey, GU16 7SR, UK.

Irish Company Address

Novartis Ireland Limited, Beech House, Beech Hill Office Campus,
Clonskeagh, Dublin 4.

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Information for the Healthcare Professional

To be injected either intramuscularly by deep intragluteal injection into the upper outer quadrant, or intravenously by slow infusion after dilution in accordance with the following instructions. Each ampoule is for single use only. The solution should be used immediately after opening. Any unused contents should be discarded.

Depending on the intended duration of infusion, mix 100 to 500 mL of isotonic saline (sodium chloride 0.9% solution) or glucose 5% solution buffered with sodium bicarbonate injectable solution (0.5 mL of 8.4% or 1 mL of 4.2% or a corresponding volume of a different concentration) taken from a freshly opened container; add the contents of one Voltarol ampoule to this solution. Only clear solutions should be used. If crystals or precipitates are observed, the infusion solution should not be used. As a rule, Voltarol solution for injection should not be mixed with other injection solutions.

Infusion solutions of sodium chloride 0.9% or glucose 5% without sodium bicarbonate as an additive present a risk of supersaturation, possibly leading to formation of crystals or precipitates. Infusion solutions other than those recommended should not be used. Intravenous infusions should be initiated immediately after preparing the infusion solutions (see above instructions). The infusion solutions should not be stored.