

VOLTAROL® Suppositories 12.5, 25, 50 and 100 mg (diclofenac sodium)

Patient Information Leaflet

What you need to know about Voltarol Suppositories

Your doctor has decided that you need this medicine to help treat your condition.

Please read this leaflet carefully before you start to use these suppositories. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Voltarol Suppositories are, and what they are used for
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1. What Voltarol Suppositories are and what they are used for

Diclofenac sodium, the active ingredient in Voltarol Suppositories, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

- Voltarol Suppositories relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:
 - Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis
 - Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
 - Tendonitis, tenosynovitis, bursitis.
- They are also used to treat pain and inflammation associated with dental and minor surgery.
- In children aged 1 to 12 Voltarol Suppositories 12.5 and 25 mg are used to treat juvenile chronic arthritis.
- In children aged over 6 they can also be used alone, or in combination with other painkillers, for the short term treatment of any pain experienced after an operation.

2. What you need to know before you use Voltarol Suppositories

Some people MUST NOT use Voltarol Suppositories. Talk to your doctor if:

- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Voltarol Suppositories. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have heart, kidney or liver failure
- 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)
- you are more than six months pregnant
- you suffer from ineffectual straining to empty the bowels, diarrhoea or rectal bleeding

You should also ask yourself these questions before using Voltarol Suppositories:

- Do you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you have a condition called porphyria?
- Do you suffer from any blood or bleeding disorder? If you do, your doctor may ask you to go for regular check-ups while you are using these suppositories.
- Have you ever had asthma?
- Are you breast-feeding?
- Do you have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides)?
- Do you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)?
- Do you have diabetes?
- Do you smoke?
- Do you have Lupus (SLE) or any similar condition?

If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Voltarol Suppositories might not be the right medicine for you.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- 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 and 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 or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- 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/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Pregnancy, breast-feeding and fertility

- Do not use Voltarol Suppositories if you are in the last 3 months of pregnancy as 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 use Voltarol Suppositories 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. If used for more than a few days from 20 weeks of pregnancy onward, Voltarol Suppositories can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
- Are you trying for a baby? Using Voltarol Suppositories 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.

Will there be any problems with driving or using machinery?

Very occasionally people have reported that Voltarol Suppositories have 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 operate machinery.

Other special warnings

- You should take the lowest dose of Voltarol for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Voltarol. 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.
- 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.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to 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.

- 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 taking Voltarol.
- **VOLTAROL Suppositories 50 mg and 100 mg are not suitable for children.**
- **VOLTAROL Suppositories 12.5 mg are not used for adults.**

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

Information about sodium content

This medicine contains less than 1mmol sodium (23mg) per suppository, that is to say essentially 'sodium free'.

3. How to use Voltarol Suppositories

The doctor will tell you how to use Voltarol Suppositories. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep using the suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Suppositories are designed for insertion into the back passage (rectum). **Never take them by mouth.**

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.

Adults

Voltarol Suppositories are normally inserted one, two or three times a day up to a maximum **total** daily dose of 150mg. The number of suppositories you need will depend on the strength which the doctor has given you.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Voltarol Suppositories are not affecting your stomach, particularly during the first 4 weeks that you are using the suppositories.

Children

For the treatment of chronic juvenile arthritis in children aged 1 to 12:

Doses vary with age, but are usually between 1 and 3 mg/kg body weight every day divided into 2 or 3 doses.

For the treatment of post-operative pain in children aged 6 and over:

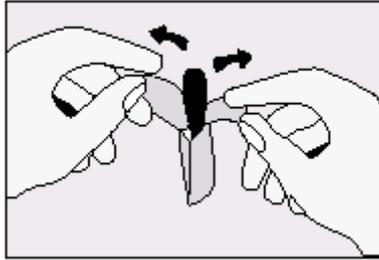
Doses vary with age, but are usually between 1 and 2 mg/kg body weight per day divided into 2 or 3 doses for no more than 4 days.

Your child's doctor will work out the dose that is suitable for your child and will tell you how many Voltarol Suppositories to use and how often. Follow his/her instructions carefully. If you are not sure about the dose, check with your doctor or pharmacist.

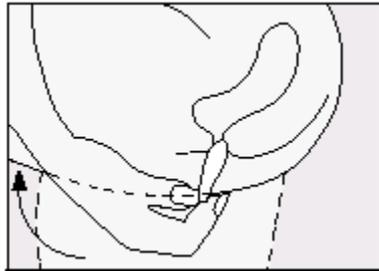
How to insert the suppositories

- Empty your bowels before inserting a suppository.
- Wash your hands.

- Take out the strip of suppositories and tear off one along the perforation.
- Then take the suppository out of the plastic wrapping by pulling back the loose end.



- Lie on one side with your knees pulled up towards your chest.
- Gently push the suppository pointed end first into your back passage (rectum) with your finger. Push the suppository in as far as possible as shown in the diagram.



- Lower your legs and, if possible, stay still for a few minutes.
- If you feel as if you need to push the suppository out, try to resist this by lying still with your buttocks pressed together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.
- Wash your hands.

The procedure is the same for a child. Once they have emptied their bowels, get them to lie down on their front or side. Gently push the suppository into the child's back passage until it disappears. Try and stop the child moving around for a few minutes to reduce the risk of the suppository coming out.

What if you forget to take a dose?

If you forget to use a suppository, do not worry. Use one as soon as you remember. If it is nearly time for your next dose though, just take the next dose and forget about the one you missed. Do not double up the next dose to make up for the one you missed. Do not insert 2 suppositories at the same time. The total dose should not be more than 150 mg each day if you are an adult. Children should not take more than the dose that is prescribed by their doctor.

What if you use too many suppositories?

You should not take more than 150 mg in one day if you are an adult. Children should not take more than the dose that is prescribed by their doctor. If you accidentally use too many suppositories or use them too often, tell your doctor or go to your nearest casualty department straight away.

4. Possible side effects

Voltarol Suppositories are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Some side effects can be serious

Stop using the suppositories and tell your doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- 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
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Voltarol Suppositories and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

Voltarol Suppositories may also occasionally cause itching or burning in your back passage or make any haemorrhoids (piles) worse.

The side effects listed below have also been reported.

Common side effects (*These may affect between 1 and 10 in every 100 patients*):

- 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
- Irritation where the suppository is inserted

Uncommon side effects (*these may affect between 1 and 10 in every 1000 patients*):

- Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

Rare side effects (*These may affect between 1 in every 1000 to 1 in every 10,000 patients*):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage

- Black, tarry faeces or stools
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

Very rare side effects (*These may affect less than 1 in every 10,000 patients*):

Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.

Effects on the chest or blood:

Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).

Effects on the liver or kidneys:

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

Effects on skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.
Hair loss.

Effects on the reproductive system:

Impotence.

Other side effects that have also been reported with unknown frequency include:

Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Do not be alarmed by this list - most people use Voltarol Suppositories without any problems.

Reporting of side effects

If you get any side effects, talk your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Voltarol Suppositories

Do not store above 30°C.

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

Do not use the suppositories after the expiry date which is printed on the outside of the pack. If your doctor tells you to stop using them, please take any unused suppositories back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Contents of the pack and other information

What Voltarol Suppositories contain

- Each suppository contains either 12.5, 25, 50 or 100 mg of the active ingredient, diclofenac sodium.
- The other excipient is hard wax, a fatty suppository base.

What Voltarol Suppositories look like and the contents of the pack

The suppositories are white to yellowish, torpedo-shaped, with smooth or slightly rough surfaces. They come in foil packs of 10.

Marketing Authorisation Holder and Manufacturer

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

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