

Package leaflet: Information for the patient

VOLTAREN® 12.5 mg suppositories.

VOLTAREN® 50 mg suppositories.

VOLTAREN® 100 mg suppositories.

diclofenac sodium

Read all of this leaflet carefully before you start taking 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 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

- 1 What Voltaren suppositories are, and what they are used for
- 2 What you need to know before you take Voltaren Suppositories
- 3 How to take Voltaren Suppositories
- 4 Possible side effects
- 5 How to store Voltaren Suppositories
- 6 Contents of the pack and other information

1 What Voltaren Suppositories are, and what they are used for

Diclofenac sodium, the active ingredient in Voltaren Suppositories, is one of 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.

- Voltaren Suppositories relieve pain, reduce swelling, reduce fever and ease inflammation in conditions affecting the joints, muscles and tendons including:
- Rheumatoid arthritis, osteoarthritis and spondyloarthritis, acute gout, ankylosing spondylitis, and other types of rheumatism
- Backache, frozen shoulder, soft tissue sports injuries, sprains and strains, dislocations and fractures
- Tendonitis, tenosynovitis, bursitis
- They are used to treat pain and inflammation associated with dental and minor surgery.

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- Voltaren Suppositories are used in painful inflammatory conditions in gynaecology, including menstrual periods.
- They are also used for painful inflammatory infections of the ear, nose and throat

Voltaren Suppositories are used in migraine attacks

In children Voltaren Suppositories are used to treat juvenile rheumatoid arthritis.

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 Suppositories

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 suppositories:

- 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 Suppositories. (These are listed at the end of the 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 allergic type 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 have 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 your rectum is painful (sometimes with bleeding and discharge).
- 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 of brain or an operation to clear or bypass blockages.
- If you have had problems with your blood circulation (peripheral arterial disease).
- If you have proctitis.

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Warnings and Precautions

Talk to your doctor or pharmacist before taking Voltaren suppositories

If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?

- If you have any kidney or liver problems, or you are elderly
- If you have a condition called porphyria
- If you suffer from any blood or bleeding disorder, your doctor may ask you to go for regular check-ups while you are taking these suppositories.
- If you have ever had asthma or hay fever (seasonal allergic rhinitis)?
- If you are breast-feeding?
- If you could be dehydrated (e.g. by sickness, diarrhoea, before or after major surgery).
- If you have swollen feet.
- If you smoke, you 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, 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 suppositories of 12.5 mg or 25 mg are recommended for use in children and adolescents below 14 years of age.

Because of their strength, Voltaren suppositories of 50 mg must not be given to children and adolescents below 14 years of age.

Voltaren suppositories of 100 mg must not be given to children and adolescents (below 18 years of age).

Voltaren suppositories must not be given to children under 12 months of age.

Other medicines and Voltaren suppositories

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

- Medicines (such as metformin) 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).

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- Ciclosporin, Tacrolimus (used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary 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 and breast-feeding

- 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 Voltaren Suppositories during the last 3 months of pregnancy as it may affect the baby's circulation. 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.
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- Are you trying for a baby? Taking Voltaren 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.
- 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.

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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.

3 How to take Voltaren Suppositories

Always take this medicine as your doctor or pharmacist has told you. Check in with your doctor or pharmacist if you are not sure

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

The recommended dose is:

Use in adults

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

In painful menstrual periods, start treatment with a dose of 50 to 100 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If the daily dose of 150 mg does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to take up to 200 mg daily during your next menstrual periods. Do not exceed 200 mg per day.

In migraine, start treatment with a dose of 100 mg as soon as you feel the first signs of an attack. This dose is usually sufficient. If pain relief is not sufficient, you may take another suppository of up to 100 mg on the same day. If you need further treatment on the following days, do not exceed 150 mg per day, taken in separate doses.

Use in 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 Voltaren Suppositories are not affecting your stomach, particularly during the first 4 weeks that you are using the suppositories.

Use in children

For the treatment of juvenile rheumatoid arthritis in children aged 2 to 14:

Doses vary with the age but are usually 2 mg/kg body weight divided into 2 or 3 doses.

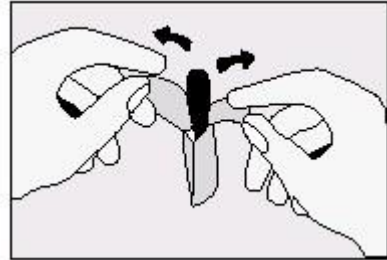
Your child's doctor will work out the dose that is suitable for your child and will tell you how many Voltaren Suppositories to use and how often. Follow his/her instructions carefully. If you are not sure about the dose, check with your doctor or pharmacist.

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.

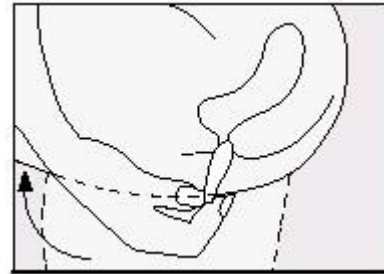
How to insert the suppositories

- 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.

If you forget to take Voltaren suppositories

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 on the next dose to make up for the one missed. Do not insert 2 suppositories at the same time. The total dose should not be more than 150mg each day if you are an adult. Children should not take more than the dose that is prescribed by their doctor.

If you take more Voltaren suppositories than you should

You should not take more than 150mg 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Voltaren suppositories 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 suppositories 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

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 (150 mg) 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 diarrhoea (signs of hemorrhagic diarrhoea).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer, bleeding or perforation).

- Diarrhoea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, ischemic 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 dermatitis exfoliative).
- 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 oedema).
- 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, diarrhoea, 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, application site irritation.

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), painful rectum (sometimes with bleeding and discharge).

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), bleeding due to hemorrhoids.

***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.

If any of these affects you severely, **tell your doctor.**

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

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.

Do not be alarmed by this list - most people take Voltaren Suppositories without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

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 Suppositories

- Keep this medicine out of the sight and reach of children
- Protect from heat (store below 30°C). Keep the suppositories in the original pack.
- Do not use this medicine after the expiry date which is stated on the carton.
- 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 Voltaren suppositories contain

The suppositories come in three strengths containing either 12.5, 50 or 100mg of the active ingredient, diclofenac sodium, in a hard fatty suppository base. **What Voltaren**

suppositories look like and contents of the packs Voltaren Suppositories 12.5mg and 50mg come in foil packs of 10.

Voltaren Suppositories 100mg come in foil packs of 5 and 10.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is
Novartis Ireland Limited Vista Building,
Elm Park, Merrion Road,
Ballsbridge, Dublin 4,
Ireland.

Voltaren Suppositories are manufactured by:
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F-68330 Huningue,
France

Batch Release Site
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Germany

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If you would like any 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