

# VOLTAREN<sup>®</sup> SUPPOSITORIES

Diclofenac Sodium (12.5 mg, 25 mg, 50 mg)

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## What Voltaren is used for

Voltaren belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation as listed below.

### *Indicated for treatment of:*

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis (systemic inflammatory disorder that affects joints), juvenile rheumatoid arthritis, ankylosing spondylitis (chronic inflammatory disease of the skeleton), osteoarthritis (degeneration joint disease) and spondylarthritis (inflammation of the joint), painful syndromes of the vertebral column, non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints).
- Acute attacks of gout.
- Post-traumatic and post-operative pain, inflammation and swelling.
- Primary dysmenorrhea (period pain).

## How Voltaren works

Voltaren relieves the symptoms of inflammation, such as pain and swelling, 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.

## Before you use Voltaren

Follow all your doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

- *When you must not use it*

- If you are allergic (hypersensitive) to diclofenac or to any of the other ingredients of Voltaren listed at the end of this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen. Reactions may include asthma, runny nose, skin rash, swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema). If you think you may be allergic, ask your doctor for advice.
- If you have stomach or intestinal ulcer.
- If you have gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.
- If you suffer from kidney or liver failure.
- If you suffer from severe heart failure.
- If you are in the last three months of pregnancy.
- If you have proctitis (inflammation of the rectum and anus)

If any of these apply to you, tell your doctor before receiving/taking/using Voltaren.

## ***Pregnancy and breast-feeding***

You should tell your doctor if you are pregnant or think that you may be pregnant. You should not receive/take/use Voltaren in any form while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not receive/take/use Voltaren in any form during the last 3 months of pregnancy, as it could harm your unborn child and cause problems at delivery. You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are receiving/taking/using Voltaren, as it might be harmful for your infant.

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

## ***Women of child-bearing potential***

Voltaren may make it more difficult to become pregnant. You should not receive Voltaren unless necessary, if you are planning to become pregnant or if you have problems to become pregnant.

### - *Before you start to use it*

Take special care

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, stroke or peripheral arterial disease), treatment with Voltaren is generally not recommended.
- If you have 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.
- If you are receiving/taking/using Voltaren simultaneously with other anti-inflammatory medicines including acetylsalicylic acid, corticosteroids, “blood thinners” or selective serotonin-reuptake inhibitors
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhea, before or after major surgery).
- If you have swollen feet.

- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.
  - If you recently had or you are going to have a surgery of the stomach or intestinal tract as taking Voltaren can sometimes worsen wound healing in your gut after surgery.
  - If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltaren or other pain medications.
- If any of these apply to you, tell your doctor before you receive/take/use Voltaren in any form.

- Taking other medicines

Tell your doctor, pharmacist or healthcare provider, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (medicines used to treat some types of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- “Blood thinners” (medicines used to prevent blood-clotting).
- Medicines used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibacterials (medicines used against infections).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).

- Rifampicin (an antibiotic medicine used to treat bacterial infections)

**How to use Voltaren**

Follow your doctor’s instructions carefully. Do not exceed the recommended dose.

- How much to use

Do not exceed the recommended dose. Dose to be individually adjusted, lowest effective dose to be given for the shortest duration.

**Adults:** 50 to 150 mg/day in divided doses (dysmenorrhoea: up to 200 mg/day).

**Children over 1 year and**

**adolescents:** 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3mg/kg/day), with a maximum daily dose of 150 mg.

◆ **Special patients population:** No adjustment of the starting dose is required.

- When to use it

It is best to use the suppositories after emptying your bowels. Suppositories are wrapped in foil. Before inserting the suppository, take off all the foil and moisten the suppository with cold water. Lie down on your side and using your finger push the suppository well up into the rectum. If the suppository is too soft to insert, chill it in the refrigerator for a few minutes or hold it under cold water *before* taking off the foil. Do not break the suppositories, as incorrect storage conditions may lead to uneven distribution of the active substance. Never take suppositories by mouth.

- How long to use Voltaren

Follow your doctor’s instructions exactly. 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. If you have questions about how long to take Voltaren, talk to your doctor or your pharmacist.

- If you forget to use Voltaren

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take it at the usual time. Do not double the next dose to make up for the one you missed.

- If you use too much (overdose)

If you have accidentally taken too much Voltaren, tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention.

**While you are using Voltaren**

- Things you must do

- 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.
- Voltaren may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are receiving/taking Voltaren.
- In very rare cases, Voltaren, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash).

If you get any of the above-described symptoms, tell your doctor straight away.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give Voltaren to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

**Driving and using machines**

Be careful driving or operating machinery until you know how Voltaren affects you.

**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.

Voltaren may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop using the medication and seek medical assistance right away.

### Side effects

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

#### ◆ Common side effects are:

Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia (indigestion), abdominal pain, flatulence, decreased appetite, transaminases increased, rash, application site irritation

#### ◆ Rare side effects are:

Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence (sleepiness), asthma (including dyspnea (difficulty breathing)), gastritis, gastrointestinal hemorrhage, hematemesis (vomiting of blood), hemorrhagic diarrhea, melena (blood in stool), gastrointestinal ulcer (with or without bleeding or perforation), hepatitis (inflammation of the liver), jaundice, liver disorder, urticaria (hives), edema (water retention), proctitis (inflammation of rectum/anus).

#### ◆ Very rare side effects are:

Blood disorders e.g. thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), mental disorder such as disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis (non-bacterial inflammation to the linings of the brain), dysgeusia (taste disturbance), cerebrovascular accident, visual impairment, vision blurred, diplopia (double vision), tinnitus (ringing in

the ears), impaired hearing, palpitations, chest pain, cardiac failure, myocardial infarction (heart attack), hypertension, vasculitis (inflammation of blood vessels), pneumonitis (inflammation at the lungs), colitis (inflammation of the colon) (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis (inflammation of the mouth), glossitis (inflammation of the tongue), esophageal disorder, intestinal diaphragm disease, pancreatitis, liver problems such as fulminant hepatitis, hepatic necrosis/ hepatic failure, skin problems such as bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia (balding), photosensitivity reaction, purpura, Hensch-Schonlein purpura, pruritus, kidney problems e.g. acute renal failure, hematuria (blood in urine), proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, haemorrhoids (piles)

#### ◆ Unknown frequency side effects:

Kounis syndrome (coincidental occurrence of chest pain and allergic reactions), a serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters and itching (signs of generalized bullous fixed drug eruption).

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

### Storage and disposal of Voltaren

#### - Storage

- Do not use after the expiry date shown on the box.
- Do not store above 30°C.
- Keep out of the reach and sight of children.

#### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### - What it looks like

White to yellowish torpedo shaped suppositories with smooth surface.

#### - Ingredients

-Active ingredient:

The active substance in Voltaren suppositories is diclofenac sodium.

-Inactive ingredient:

The other ingredient is hard fat.

#### - MAL Number

Voltaren Suppositories 12.5mg:

MAL19861075ACRZ

Voltaren Suppositories 25mg:

MAL19861076ACRZ

Voltaren Suppositories 50mg:

MAL19870250ACRZ

### Manufacturer:

Delpharm Huningue S.A.S.,  
Huningue, France for Novartis Pharma AG, Basle, Switzerland.

### Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.

Level 18, Imazium,  
No. 8, Jalan SS21/37,  
Damansara Uptown,  
47400 Petaling Jaya, Selangor

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NPRA