

VOLTAREN[®] TABLET

Diclofenac Sodium (50 mg)

What is in this leaflet

1. What Voltaren is used for
2. How Voltaren works
3. Before you use Voltaren
4. How to use Voltaren
5. While you are using Voltaren
6. Side effects
7. Storage and Disposal of Voltaren
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

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 (degenerative 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 dysmenorrhoea (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 the 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, diclofenac or ibuprofen. Reactions may include asthma, runny nose, skin rash, face swelling. 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 severe kidney or liver disease.
- If you suffer from severe heart failure.
- If you are in the last three months of pregnancy.

If any of these apply to you, tell your doctor without receiving/taking/using Voltaren. If you think you may be allergic, ask your doctor for advice.

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.

Ask your doctor or pharmacist for advice before taking any medicines.

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

- *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, as 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 any of these apply to you, tell your doctor before you receive/take/use Voltaren in any form.

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.

- Taking other medicines

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

- 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).

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 recommended to take the tablets before meals or on an empty stomach. It should be swallowed whole with a glass of water or other liquid. Do not divide or chew the tablets.

- 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 it

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 the next tablet 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

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Voltaren.

Tell your doctor immediately if you become pregnant while taking this medicine.

- 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.

Voltaren contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

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, abdominal pain, flatulence, decreased appetite, transaminases increased, rash,

◆ **Rare side effects are:**

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

◆ **Very rare side effects are:**

Blood disorders like thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability,

psychotic disorder (disturbing moods), paresthesia (numbness), memory impairment, convulsion (seizure), anxiety, tremor, meningitis aseptic (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), hearing impaired, palpitations (fast heartbeat), chest pain, cardiac failure, myocardial infarction (heart attack), hypertension (high blood pressure), vasculitis (inflammation of blood vessels), pneumonitis (inflammation of lungs), colitis (inflammation of the colon) (including hemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis (inflammation of mouth), glossitis (inflammation of the tongue), esophageal disorder, intestinal diaphragm disease, pancreatitis (inflammation of pancreas), liver disorders such as hepatitis fulminant, hepatic necrosis/ hepatic failure, skin conditions such as dermatitis bullous, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, alopecia (balding), photosensitivity reaction, purpura, Henocho-Schonlein purpura, pruritus (itchiness), kidney problems e.g. renal failure acute, hematuria (blood in urine), proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis.

If you notice any side effects or 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 calling Tel: 03-78835550, or visiting the website

portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Voltaren

- Storage

- Do not use after the expiry date shown on the box.
- Do not store above 30°C.
- Store in the original package in order to protect from light
- 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

Voltaren 50mg tablets: Light brown round tablet with slightly convex faces and bevelled edges with imprint "GT" on the first side and "CG" on the second side.

- Ingredients

The active substance in Voltaren Gastro-resistant tablet is diclofenac sodium.

The other ingredients are:

- **Voltaren 50mg Gastro-resistant tablets:** Cellulose microcrystalline; lactose monohydrate; magnesium stearate; maize starch; povidone; silica, colloidal anhydrous; sodium starch glycolate (type A); hypromellose; iron oxide red (E172); iron oxide yellow (E172); macroglycerol hydroxystearate; Methacrylic acid – ethyl acrylate copolymer; macrogol 8000; talc; titanium dioxide (E171);Silicone antifoam emulsion SE 2.

- MAL Number

Voltaren Gastro-resistant Tablet 50mg: MAL19861068ARZ

Manufacturer:

Novartis Saglik Gida Ve Tarim, Kurtkoy, Turkey

Product Registration Holder

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