

Package leaflet: Information for the patient

VOLTAREN® 25 mg gastro-resistant tablets.

VOLTAREN® 50 mg gastro-resistant tablets.

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 any of the 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

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

Diclofenac sodium, the active ingredient in Voltaren Tablets, 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 Tablets 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.
- Voltaren Tablets 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
- In children Voltaren Tablets 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 Tablets

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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Do not take Voltaren Tablets:

- 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 Tablets. (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 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)

Warnings and Precautions

Talk to your doctor or pharmacist before taking Voltaren

- 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 tablets.

- If have you ever had asthma or hay fever (seasonal allergic rhinitis)
- If you are breast-feeding
- If you have an inherited intolerance to some sugars such as lactose (Voltaren Tablets contain a small amount of lactose)
- If you could be suffering from dehydration (e.g. by sickness, diarrhea, before or after major surgery)
- If you have swollen feet
- If you smoke, 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 dose for the shortest duration necessary.

Use in children and adolescents

Because of their strength, Voltaren 50 mg tablets must not be given to children and adolescents below 14 years of age. For example, Voltaren 25 mg tablets could be used for patients below 14 years of age. Voltaren tablets must not be given to children under 12 months of age.

Other medicines and Voltaren

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).
- Ciclosporin, 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, 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).

Voltaren with food and drink

Swallow the tablets whole with a drink of water. Do not crush or chew the tablets.

Take the tablets before or on an empty stomach.

Pregnancy, breast-feeding and fertility

- 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 Tablets 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.
- Are you trying for a baby? Taking Voltaren Tablets 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 D during pregnancy or breast-feeding.

Voltaren 25 and 50 mg tablets contain lactose

Voltaren 25 and 50 mg tablets 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.

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.

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 Tablets

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

The recommended dose is:

Use in adults and children over 16

At the beginning of treatment the daily dose is generally 100 to 150 mg. In milder cases, and for long-term treatment, 75 to 100 mg daily is usually sufficient. The daily dose should usually be divided into 2 to 3 separate doses. Do not exceed 150 mg per day. 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.

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 Tablets are not affecting your stomach.

Use in children aged 2-16 years

Doses vary with the age and weight of the child. The usual dose is 0.5 mg to 2 mg per kilogram of body weight a day. This is usually divided into two or three separate doses.

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.

When to take Voltaren

It is recommended to take Voltaren GR tablets before meals or on an empty stomach.

If you forget to take Voltaren

If you forget to take a dose, take 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 take more than 150 mg (three 50 mg tablets or six 25 mg tablets) in 24 hours.

If you take more Voltaren than you should

If you, or anyone else, accidentally take too much, tell your doctor or your nearest hospital casualty department. Take your medicines pack with you so that people can see what you have taken.

4 Possible side effects

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

Stop using Voltaren 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 and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of the 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).
- Difficult of hearing (signs of impaired hearing)
- Sudden and oppressive chest pain (signs of Myocardial infarction or heart attack).
- 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 diarrhea (signs of hemorrhagic diarrhea).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer, bleeding or perforation).

- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, ischaemic 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 exfoliative dermatitis).
- 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 edema).
- 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, diarrhea, 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,

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),

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).

***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.

Do not be alarmed by this list - most people take Voltaren Tablets 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.

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.

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 Tablets

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

Voltaren 25mg: protect from heat (store below 30°C) and moisture

Voltaren 50mg: protect from heat (store below 30°C)

Keep the tablets in their original pack.

Do not use this medicine after the expiry date which is stated on the carton.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to you 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 Tablets contain

The tablets come in two strengths containing either 25 mg or 50 mg of the active ingredient, diclofenac sodium. The tablets are enteric-coated. This special coating

prevents absorption of diclofenac sodium in the stomach, reducing the risk of stomach irritation. It is absorbed when it reaches the intestine.

- **Core for 25 mg and 50 mg:** Cellulose microcrystalline; lactose monohydrate; magnesium stearate; maize starch; povidone; silica, colloidal anhydrous; sodium starch glycolate (type A);
- **Coating for 25 mg:** hypromellose; iron oxide yellow (E172); macroglycerol hydroxystearate; Methacrylic acid – ethyl acrylate copolymer; macrogol 8000; talc; titanium dioxide (E171); Simeticone; alpha-octadecyl-omega-hydroxy-polyglycolether; sorbic acid.
- **Coating for 50 mg:** hypromellose; iron oxide red (E172); iron oxide yellow (E172); macroglycerol hydroxystearate; Methacrylic acid – ethyl acrylate copolymer; macrogol 8000; talc; titanium dioxide (E171); Simeticone; alpha-octadecyl-omega-hydroxy-polyglycolether; sorbic acid.

What Voltaren Tablets look like and contents of the packs

The 25mg tablets come in blister packs containing 30 or 84 tablets.

The 50mg tablets come in blister packs containing 14, 20 or 84 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised on 09/2024

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