

Package leaflet: Information for the patient
VOLTAREN® SR 75 and
VOLTAREN® Retard 100
diclofenac sodium

Read all of this leaflet carefully before you start taking your 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 affects 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 Tablets are, and what they are used for
- 2 What you need to know before you take Voltaren Tablets
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- 4 Possible side effects
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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 SR Tablets and Voltaren Retard Tablets are specially formulated to release the diclofenac sodium slowly.

- Voltaren Tablets relieve pain, reduce swelling, reduce fever and ease inflammation in conditions affecting the joints, muscles and tendons including:
- Rheumatoid arthritis, osteoarthritis and spondylarthritis, 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.

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.

Voltaren tablets contain sucrose and sodium

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

This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 had problems with your blood circulation (peripheral arterial disease)

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- 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.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Voltaren PR Tablets

- 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 you have ever had asthma or hay fever (seasonal allergic rhinitis)
- If you are you breastfeeding
- If you could be suffering from dehydration (e.g. by sickness, diarrhoea, 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltaren tablets or other pain medications.
- If you think you may be allergic, ask your doctor for advice

Side effects may be minimized by using the lowest effective dose for the shortest duration necessary.

Children and adolescents

Because of their dosage strengths, Voltaren 75 mg and 100 mg tablets must not be given to children and adolescents (below 18 years of age).

Other medicines and Voltaren Tablets

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicine

- Medicines (such as metformin) to treat diabetes

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- Anticoagulants (blood thinning tablets like warfarin)
 - Diuretics (water tablets).
 - Lithium (used to treat some mental problems).
 - Methotrexate (for some inflammatory diseases and some cancers).
 - Cyclosporin, 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).

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.
- 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.

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 Tablets 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 as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water. Do not crush or chew them as this will affect the special 'slow release' system.

The recommended doses are:

Adults

75 mg to 150 mg daily divided into two or three doses. The number of tablets which you take 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 150 mg per day.

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 and adolescents

These tablets are not suitable for children

When to take Voltaren

Where the symptoms are most pronounced during the night or in the morning, Voltaren PR tablets should preferably be taken in the evening.

Voltaren PR tablets should be swallowed whole with a glass of water or other liquid. It is recommended to take Voltaren PR tablets during meals. Do not divide or chew the tablets.

If you have questions about how long to take Voltaren, talk to your doctor or your pharmacist.

If you forget to take Voltaren Tablets

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 in 24 hours.

If you take more Voltaren tablets 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 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
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).

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 (150mg) 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).

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- 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 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 and ischaemic colitis, 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).

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- 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.

not known (frequency cannot be estimated from the available data)

- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

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 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 Malta ADR Reporting Website: <https://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 reach and sight of children.
- Voltaren SR Tablets: protect from heat (store below 30°C) and moisture.
- There are no special storage instructions for Voltaren Retard Tablets.
- Do not take Voltaren Tablets after the expiry date which is printed on the outside of the pack. 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 SR & Retard tablets contain

The active ingredient is diclofenac potassium

The tablets also contain the inactive ingredients silica aerogel, cetyl alcohol, magnesium stearate, povidone, sucrose, hydroxypropyl methylcellulose, red iron oxide, polysorbate 80, talc, titanium dioxide, macrogol 8000.

What Voltaren SR & Retard tablets look like and contents of the pack

Voltaren SR Tablets are pale pink, triangular tablets marked “ID” on one side and “CG” on the other containing 75mg of the active ingredient, diclofenac sodium.

Voltaren Retard Tablets are pink, round tablets debossed “CGC” on one side and “CG” on the other containing 100mg of the active ingredient, diclofenac sodium.

Voltaren Retard Tablets come in blister packs containing 10, 28, 70 tablets.

Voltaren SR Tablets come in blister packs containing 10, 20, 28, 56, 70 or 100 tablets. Some of these pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

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