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## **Package leaflet: Information for the patient**

### **VOLTAREN® D Dispersible tablets 50mg**

diclofenac free acid

**Please read this leaflet carefully before you start taking your medicine. 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. 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.

#### **What is in this leaflet**

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

#### **1. What Voltaren D Dispersible Tablets are and what they are used for**

Diclofenac sodium, the active ingredient of Voltaren D, 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. Voltaren D act quickly and so are used to treat short-term painful conditions affecting the joints and muscles. They are especially useful for the treatment of sprains, strains and back pain and also reduce fever. They should not be taken for more than three months. They have no effect on the causes of inflammation or fever.

Voltaren D can be used for short-term treatment of the following conditions:

- Pain and swelling after surgery.
- Sprains, strains or other injuries.
- Flare-ups of degenerative pain (arthritis).
- Gout attacks.
- Back pain, frozen shoulder, tennis elbow, and other types of rheumatism.
- Painful inflammatory conditions in gynaecology, including painful menstrual periods.
- Infections of the ear, nose, or throat.

## **Monitoring during your treatment with Voltaren D**

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 D, 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 D needs to be discontinued or if the dose needs to be changed.

## **2. What you need to know before you take Voltaren D**

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 D as Voltaren D can sometimes worsen wound healing in your gut after surgery.

### **Voltaren D tablets contain sodium**

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

### **Do not take Voltaren D:**

- 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 D. (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 had 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)

If any of these apply to you, **tell your doctor without taking Voltaren D Dispersible Tablets.**

If you think you may be allergic, ask your doctor for advice.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Voltaren D

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including high blood pressure, congestive heart failure, established ischaemic heart disease or peripheral arterial disease)
- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- If you have 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 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, have diabetes, angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides. If so, you must not increase the dose above 100mg per day if you are treated for more than 4 weeks.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltaren D or other pain medications.

If any of these above apply to you, **tell your doctor before you take Voltaren D.**

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.

Use of Voltaren D is recommended only for short term treatment.

## **Other medicines and Voltaren D**

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 or COX-2 (cyclo-oxygenase-2) inhibitor, 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 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).

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

### **Voltaren D with food and drink**

It is recommended to take Voltaren D before meals and 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 D 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 D 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.

### **Other special warnings**

- You should take the lowest of Voltaren D 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 D. 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.
- Voltaren D are not suitable for children.
- If, at any time while taking Voltaren D 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.

### **3. How to take Voltaren D**

The doctor will tell you how many Voltaren D Dispersible Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Take the tablets before or with food.

Drop the tablets into a glass of water and stir. Drink the liquid at once. To make sure you get all of the medicine, rinse the glass round with a small amount of water and drink this as well.

The usual doses are:

#### **Adults**

One tablet two or three times a day.

In painful menstrual periods, start treatment with a single dose of 1 to 2 Voltaren Dispersible Tablets as soon as you feel the first symptoms. Continue with 1 Voltaren Dispersible Tablet up to three times a day for a few days, as needed. If the maximum daily dose of 3 Voltaren Dispersible Tablets does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to take up to 4 Voltaren Dispersible Tablets daily during your next menstrual periods. Do not take more than 4 Voltaren Dispersible Tablets 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 Dispersible Tablets are not affecting your stomach.

**These tablets are not suitable for children and adolescents below 14 years of age.**

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.

#### **If you forget to take Voltaren D**

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 you missed. Do not take more than 150mg (three tablets) in 24 hours.

#### **If you take more Voltaren D than you should**

If you, or anyone else, accidentally take too much, **tell your doctor or your nearest hospital casualty department.** Take your medicine 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 D 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 D 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).
- 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).
- Diarrhea, 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 dermatitis bullous).
- 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-Schoenlein 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), injection site abscess.

\*Vision disorders: If symptoms of vision disorders occur during treatment with Voltaren D 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 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 D 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 D 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](http://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 D**

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

Protect from heat (store below 25°C) and moisture. 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 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 D contains**

- The active substance of Voltaren D is diclofenac free acid.
- The other ingredients are microcrystalline cellulose, sodium carboxymethyl starch, croscarmellose sodium, silica aerogel, hydrogenated castor oil, and talc.

### **What Voltaren D looks like and contents of the pack**

They come in aluminium blister packs containing 20 tablets.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Novartis Ireland Limited Vista Building,  
Elm Park, Merrion Road,  
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#### **Manufacturer**

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