Package Leaflet: Information for the user

VOLTAROL® Retard 75 mg and 100 mg Film-coated prolonged release 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 onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- This medicine will be referred to as Voltarol in this leaflet.

What is in this leaflet

1. What Voltarol is and what it is used for
2. What you need to know before you take Voltarol
3. How to take Voltarol
4. Possible side effects
5. How to store Voltarol
6. Contents of the pack and other information

1. What Voltarol is and what it is used for

Diclofenac sodium, the active ingredient in Voltarol is one of a group of medicines called "non-steroidal anti-inflammatory drugs" (NSAIDs). NSAIDs reduce pain and inflammation. They have no effect on the causes of inflammation.

Voltarol is used to treat a number of painful conditions including:
- joint, muscle or tendon pain
- attacks of gout
- pain and swelling after surgery
- sprains, strains and other injuries
- gynaecology problems such as period pain.

2. What you need to know before you take Voltarol

Do not take Voltarol if:
- you think you may be allergic to diclofenac sodium or to any of the other ingredients of Voltarol (listed in Section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the gut (digestive tract). This can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black tarry stools. This may have been when you used an NSAID before
- you are in the last three months of pregnancy
- you have severe kidney or liver problems

- you have ever had an allergic reaction (such as asthma, wheezing, skin rash, swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema), runny nose) after taking medicines to treat pain or swelling (NSAIDs) such as aspirin or ibuprofen
- you have heart disease (e.g. if you have had a heart attack, have angina or blockages in the arteries of your heart)
- you have cerebrovascular disease (e.g. if you have had a stroke, mini-stroke or have blockages of the arteries to the brain)
- you have peripheral arterial disease (e.g. poor circulation or blockages of the arteries to the legs and feet)
- you have severe heart failure
- Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Voltarol, as Voltarol can sometimes worsen wound healing in your gut after surgery.

Do not take Voltarol if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking Voltarol.

Warnings and precautions

Talk to your doctor or pharmacist before taking your medicine if:

- if you have diabetes
- if you smoke
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- you have bowel problems such as ulcerative colitis or Crohn's disease
- you have kidney or liver problems
- you have any blood or bleeding problems – your doctor will take regular blood tests
- you have a condition called porphyria
- you have ever had asthma, other breathing problems (such as chronic obstructive pulmonary diseases, COPD) or often get chest infections
- you have ever had hay fever or nasal polyps
- you have any allergies
- you could be dehydrated
- you have ever had stomach or bowel problems.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltarol or other pain medications

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before taking Voltarol.

If you have significant risk factors for cardiovascular disease 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 Voltarol you must use the lowest effective dosage for the shortest duration necessary.

Look out for serious side effects

Voltarol can cause some serious side effects. These are listed at the beginning of Section 4. You will need to look out for these while you are taking Voltarol. If you get a serious side effect you need to stop

taking Voltarol and talk to your doctor straight away. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Risk of heart attack or stroke with Voltarol
There is a small increased risk of heart attack or stroke when you are taking any medicine like Voltarol. The risk is higher when you are taking higher doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for. If, at any time while taking Voltarol 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.

Signs of infection
Because it is an anti-inflammatory medicine, Voltarol 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 Voltarol.

Tests and checks

If you have significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Voltarol.

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor the function of your liver, kidney or your blood count. Your doctor will take these blood tests into consideration to decide if Voltaral needs to be discontinued or if the dose needs to be changed.

If you are elderly or underweight
If you are elderly or underweight you may be more sensitive to the effects of Voltarol than other adults. Follow the doctor's instructions carefully and take the smallest amount of tablets that give you relief, for the shortest possible time. Tell your doctor straight away if you get any side effects, especially stomach problems.

Children and adolescents
This medicine is not recommended for use in children or adolescents. Lower strength tablets are available for these age groups.

Other medicines and Voltarol
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription or herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- medicines 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 (medicines primarily used in patients who have received organ transplant
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- quinolone antibiotics (for infections)
- voriconazole (for fungal infections)
- any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- digoxin (used to treat heart problems)
- medicines known as SSRIs used to treat depression
- oral steroids (an anti-inflammatory drug)
- phenytoin (used to treat seizures)
- medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors.
- colestipol and cholestyramine (used to treat high cholesterol). These medicines can reduce the effect of Voltarol. Take Voltarol at least 1 hour before or 4 to 6 hours after taking these medicines
- Rifampicin (an antibiotic medicine used to treat bacterial infections).

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before taking Voltarol.

Fertility, pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

- Taking Voltarol may make it more difficult to get pregnant. You should talk to your doctor if you are planning to become pregnant or if you have problems getting pregnant.
- Do not take Voltarol if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect you and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Voltarol 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. If taken for more than a few days from 20 weeks of pregnancy, Voltarol can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
- Do not breast-feed if you are taking Voltarol. This is because small amounts may pass into the mother's milk.

Driving and using machines

Very occasionally people have reported that Voltarol has made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way you should not drive or use any tools or machines.

Voltarol 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.

Voltarol and Sodium

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

3. How to take Voltarol

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

Taking this medicine
You should take Voltarol by mouth. Swallow the tablets with a drink and with a meal. Do not crush, chew or suck the tablets as this will affect their special "controlled release" system.

- The doctor may also prescribe another medicine 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 medicines as well.
- If you are worse during the night or in the morning then take Voltarol in the evening.
- The number of tablets you need will depend on the strength the doctor has given you.

How much to take

Adults

- The recommended starting dose is 100 mg to 150 mg each day, taken as one 100 mg tablet or two 75 mg tablets.
- In mild cases, as well as for long term treatment, 75mg to 100 mg each day is usually enough.
- Do not take more than 150 mg in one day.

The elderly
Your doctor may give you a dose that is lower than the usual adult dose if you are elderly.

Children and adolescents
This medicine is not recommended for use in children or adolescents. Lower strength tablets are available for these age groups.

If you forget to take Voltarol
If you forget to take a dose, take one as soon as you remember it. If it is nearly time for your next dose though, just take the next dose and forget about the one you missed. Do not take a double dose to make up for a forgotten dose.

If you take more Voltarol than you should
If you accidentally take too much Voltarol, tell your doctor or go to your nearest hospital casualty department straight away. Take your medicine pack with you so that people can see what you have taken. The following effects may happen: vomiting, bleeding in your stomach, diarrhoea, feeling dizzy, hearing problems or fits. In severe overdose kidney or liver problems can happen.

If you stop taking Voltarol
Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Voltarol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Some side effects could be serious. Stop taking Voltarol and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Chest pain or tightness with shortness of breath (*may affect between 1 and 10 in every 1000 patients*)
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (*may affect between 1 and 10 in every 1000 patients*)
- Vomiting of blood, bleeding from the bowel (*may affect from less than 1 to 10 in every 10,000 patients*)
- Sudden slurred speech, facial drooping, weakness, disorientation, or speech problems (*may affect from less than 1 to 10 in every 10,000* patients)
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath ("bronchospasm"), swollen face, lips hands or fingers, hypotension (low blood pressure) and fainting (*may affect from less than 1 to 10 in every 10,000 patients)*
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Voltarol 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).

The following side effects have also been reported in patients taking Voltarol

- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath ("bronchospasm"), swollen face, lips, hands or fingers, hypotension (low blood pressure) and fainting
- stomach pain, indigestion, heartburn, wind, feeling sick (nausea), or being sick (vomiting)
- any sign of bleeding in your stomach or intestine, for example, when emptying your bowels, blood in vomit, or black tarry faeces
- yellowing of your skin or the whites of your eyes
- pain in your abdomen and lower back, with feeling or being sick or loss of appetite (possible signs of pancreatitis)
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance
- bruising more easily than usual
- frequent sore throats or infections
- fits, headaches together with a dislike of bright lights, fever and a stiff neck
- headache and dizziness (signs of high blood pressure, hypertension)
- serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome
- sudden severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (possible signs of stroke)

Stop taking Voltarol and see a doctor straight away if you notice any of these side effects.

Other side effects

Common (may affect up to 1 in 10 people)

- stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- headache, dizziness, vertigo
- skin rash or spots
- raised levels of liver enzymes in the blood.

Uncommon (may affect between 1 and 10 in every 1000 people)

- Palpitations (fast or irregular heartbeat), chest pain, cardiac failure.

Rare (may affect up to 1 in 1,000 people)

- stomach ulcers or bleeding (there have been very rarely reported cases resulting in death, particularly in the elderly)
- drowsiness, tiredness
- skin rash and itching
- fluid retention, symptoms of which include swollen ankles.

Very rare (may affect up to 1 in 10,000 people)

Effects on the nervous system:
Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and loss of memory.

Effects on the stomach and digestive system:
Constipation, inflammation of the tongue, taste changes, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon).

Effects on the heart, chest or blood:
Inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia).

Effects on the liver or kidneys:
Kidney or liver disorders, presence of blood or protein in the urine.

Effects on skin or hair:
Skin rashes which may be made worse by exposure to sunlight, hair loss.

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 get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol

- Keep this medicine out of the sight and reach of children.
- Do not take Voltarol after the expiry date which is stated on the blister pack and carton after 'EXP'. The expiry date refers to the last day of that month.
- Store in the original package.
- Do not store above 30°C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Voltarol Retard tablets contain

- The active substance is diclofenac sodium. Each 75 mg prolonged release tablet contains diclofenac sodium 75 mg. Each 100 mg prolonged release tablet contains diclofenac sodium 100 mg.
- The other ingredients are sucrose, cetyl alcohol, povidone, magnesium stearate, silica colloidal anhydrous, hypromellose, purified talc, polysorbate 80, titanium dioxide (E171), red iron oxide (E 172), polyethylene glycol 8000.

What Voltarol Retard tablets look like and contents of the pack

- Voltarol Retard tablets are film-coated prolonged release tablets.
- Voltarol 75mg tablets are pale pink, triangular tablets with 'CG' on one side and 'ID' on the other side. Voltarol 100mg tablets are pink, round tablets with 'CGC' on one side and 'CG' on the other side.
- Voltarol Retard tablets come in blister packs of 30.

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