

PACKAGE LEAFLET: INFORMATION FOR THE USER

VOLTAROL® RAPID 50 mg TABLETS
(diclofenac potassium)

Your medicine is known as VOLTAROL® RAPID 50 mg TABLETS but will be referred to as Voltarol Rapid Tablets throughout the following patient information leaflet.

What you need to know about Voltarol Rapid Tablets

Your doctor has decided that you need this medicine to help treat your condition.

Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT VOLTAROL RAPID TABLETS ARE AND WHAT THEY ARE USED FOR

Diclofenac potassium, the active ingredient in Voltarol Rapid Tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Voltarol Rapid Tablets relieve pain, reduce swelling and ease inflammation in:

- Rheumatoid arthritis, osteoarthritis, acute gout, low back pain, ankylosing spondylitis
- Migraine
- Conditions affecting the joints and muscles such as sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations, and fractures
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with orthopaedic, dental and other minor surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VOLTAROL RAPID TABLETS

Some people MUST NOT take Voltarol Rapid Tablets. Talk to your doctor if:

- you think you may be allergic to diclofenac potassium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Voltarol Rapid Tablets. (These are listed at the end of the leaflet.) 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 digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have heart, kidney or liver failure
- 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)
- you are more than six months pregnant.

You should also ask yourself these questions before taking Voltarol Rapid Tablets:

- Do you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you have a condition called porphyria?
- Do you suffer from any blood or bleeding disorder? If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- Have you ever had asthma?
- Are you breast-feeding?
- Do you have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides)?
- Do you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, or high cholesterol or are a smoker)?
- Do you have diabetes?
- Do you smoke?
- Do you have Lupus (SLE) or any similar condition?

If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Voltarol Rapid Tablets might not be the right medicine for you.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- 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 and 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
- Mifepristone (a medicine used to terminate pregnancy)
- 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/cholestyramine (used to lower cholesterol)

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.*

Pregnancy, breast-feeding and fertility

- Do not take Voltarol Rapid Tablets 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 your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Voltarol Rapid Tablets 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 onward, Voltarol Rapid Tablets 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.
- Are you trying for a baby? Taking Voltarol Rapid 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.

Will there be any problems with driving or using machinery?

Very occasionally people have reported that Voltarol Rapid Tablets have 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 operate machinery.

Other special warnings

- You should take the lowest dose of Voltarol for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Voltarol. 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.
- 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.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to 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.
- 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.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Voltarol Rapid, as Voltarol Rapid can sometimes worsen wound healing in your gut after surgery.

Voltarol Rapid Tablets contain 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.

Information about sodium content

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

3. HOW TO TAKE VOLTAROL RAPID TABLETS

The doctor will tell you how many Voltarol Rapid 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 with or after food.

Voltarol Rapid Tablets are specially formulated to act quickly. Swallow the tablets whole with a drink of water. Do not crush or chew them.

The usual doses are:

Adults

75 mg to 150 mg daily divided into two or three doses. The number of tablets you take will depend on the strength the doctor has given you.

For the relief of migraine in adults:

Take 50 mg at the first signs of an attack. If the migraine has not gone after 2 hours, take another 50 mg. You can take further doses at intervals of 4 to 6 hours if necessary, but you must not take more than 200 mg in a 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 Voltarol Rapid Tablets are not affecting your stomach.

Children over 14

75 mg to 100 mg daily divided into two or three doses.

Voltarol Rapid Tablets are not recommended for children under 14. They are not recommended for the treatment of migraine in children of any 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.

What if you forget to take a dose?

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.

What if you take too many tablets?

If you, or anyone else, accidentally takes 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

Voltarol Rapid Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Some side effects can be serious

Stop taking Voltarol Rapid Tablets and tell your doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke.
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- 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
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Voltarol Rapid Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

The side effects listed below have also been reported.

Common side effects (These may affect between 1 and 1 in 10 in every 100 patients):

- 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 side effects (These may affect between 1 and 10 in every 1000 patients):

- Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

Rare side effects (These may affect between 1 in every 1000 to 1 in every 10,000 patients):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

Very rare side effects (These may affect less than 1 in every 10,000 patients):

Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.

Effects on the chest or blood:

Hypertension (high blood pressure), hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

Hair loss.

Effects on the reproductive system:

Impotence.

Other side effects that have also been reported with unknown frequency include:

Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

Do not be alarmed by this list - most people take Voltarol Rapid Tablets without any problems.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE VOLTAROL RAPID TABLETS

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Voltarol Rapid Tablets should not be stored above 30°C. Store in the original package.
- Do not use after the expiry date printed on the carton label or blister strip.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Voltarol Rapid Tablets contain

- Each coated tablet contains 50 mg of the active ingredient, diclofenac potassium.
- Voltarol Rapid Tablets also contain the following inactive ingredients: colloidal anhydrous silica, magnesium stearate, maize starch, povidone, sodium starch glycollate, microcrystalline cellulose, red iron oxide (E172), macrogol 8000, sucrose, talc, titanium dioxide (E171) and calcium phosphate.

What Voltarol Rapid Tablets look like and contents of the pack

Voltarol Rapid Tablets come as unmarked, round, brownish-red, biconvex, coated tablets.

Voltarol Rapid Tablets are available as blister packs of 30 tablets

Product Licence holder

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Manufacturer

This product is manufactured by

- Novartis Farmaceutica SA, Barbera del Valles, Spain.
- Novartis Urunleri, Kurtkoy, Turkey.
- Novartis Farma S.p.A., Officina di Torre Annunziata, Naples, Italy.

For further information on your medicine, please contact the Product Licence holder: S&M Medical Ltd., at Tel: 02087997607.

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