

Package leaflet: Information for the user

Diclovol® 75 mg SR Tablets (diclofenac sodium)

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 Diclovol Tablets are and what they are used for

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

- Diclovol Tablets relieve pain, reduce swelling and ease inflammation in a wide range of conditions:
 - Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis.
 - Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures.
 - Tendonitis, tenosynovitis, bursitis.
- They are also used to treat pain and inflammation associated with orthopaedic (bone and joint surgery), dental and minor surgery

2. Before you take Diclovol Tablets

DO NOT take Diclovol Tablets. Talk to your doctor if you:

- **are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Diclovol Tablets.**
(These are listed at the end of the leaflet).
Signs of an allergic reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- 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).
- 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.
- have or have had problems with your blood circulation (peripheral arterial disease).
- have had stomach or bowel problems after you have taken other NSAIDs.
- have severe heart, kidney or liver failure.
- are more than six months pregnant.
- are having an acute attack of porphyria.

Talk to your doctor before taking Diclovol Tablets if any of the following apply to you:

- any stomach or bowel disorders including ulcerative colitis or Crohn's disease.
- kidney or liver problems or you are elderly.
- a condition called porphyria.
- 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.
- asthma, allergic rhinitis (including hay fever), nasal polyps (swelling or lumps in your nose), problems with your lungs including a long-term chest infection or had an allergic reaction to anything.
- angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- heart problems or have had a stroke or you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or you are a smoker).
- you smoke.
- you have diabetes.
- Lupus (SLE) or any similar condition.
- if you have been told by your doctor that you have an intolerance to some sugars (Diclovol Tablets contain a small amount of sucrose).

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 Diclovol, as Diclovol can sometimes worsen wound healing in your gut after surgery.

If you can say ‘yes’ to any of the above, ask your doctor or pharmacist for advice before taking this medicine. It may not be suitable for you or you may need to take special care when taking it.

Taking other medicines

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

There may be problems if you take Diclovol Tablets with certain other medicines.

Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes.
- Medicines that affect blood clotting (e.g. anticoagulants to “thin” your blood such as warfarin or anti-platelet agents such as aspirin).
- Diuretics (water tablets).
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin and tacrolimus (for some inflammatory diseases and after transplants).
- Quinolone antibiotics (for infections).
- Any other NSAID or COX-2 inhibitor, for example aspirin, ibuprofen or celecoxib).
- Mifepristone (used to terminate pregnancy).
- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Medicines known as SSRIs, and an SNRI, venlafaxine, used to treat depression.
- Corticosteroids (anti-inflammatory drugs).
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors.
- Ritonavir and zidovudine (used to treat HIV AIDS).
- Baclofen, a muscle relaxant often used in MS.
- Drospirenone (used in an oral contraceptive pill).
- Ketorolac (used to treat post-operative pain).
- Penicillamine, a treatment for rheumatoid arthritis.
- Erlotinib (for cancer).
- Iloprost, a treatment for pulmonary hypertension (high blood pressure in the artery carrying blood from the heart to the lungs).
- Pentoxifylline (used to treat circulation disorders).
- Sibutramine (for obesity).
- Sulfinpyrazone (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
- Phenytoin, a treatment for epilepsy.

Pregnancy, breast-feeding and fertility.

Do not take Diclovol 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 Diclovol 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, Diclovol 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.

Taking Diclovol Tablets may make it more difficult for you to get pregnant.

You should talk to your doctor if you are planning to become pregnant or if you have problems getting pregnant.

If you are breast-feeding, avoid taking this medicine because very small amounts of diclofenac sodium have been found in breast milk.

Driving or using machinery

Very occasionally people have reported that Diclovol 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 Diclofenac 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 Diclofenac. The risk is greater 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. Do not exceed the recommended dose or duration of treatment.
- Your doctor may want to give you an occasional check-up whilst you are taking this medicine.
- 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.
- Diclofenac 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 Diclofenac.

3. How to take Diclovol Tablets

Your doctor will tell you how many Diclovol 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. If you have any problems, talk to your doctor.

Swallow the tablets whole with a drink of water. Do not crush or chew the tablets. If possible, take the tablet at meal times.

Your doctor may prescribe another medicine at the same time to protect your stomach, particularly if you have ever had stomach problems before, you are elderly or you are taking certain other medicines as well.

Adults and children over 12

One tablet, taken once or twice daily.

Elderly

Your doctor may give you a lower dose than the usual adult dose. He or she may want to check regularly that the Diclovol Tablets are not affecting your stomach.

Children aged 1–12 years

Diclovol 75 mg SR Tablets are not recommended for children

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, 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 (two tablets) in 24 hours.

If you take too many tablets

If you, or anyone else, accidentally take too many tablets (an overdose) tell your doctor or your nearest hospital casualty department. Take the medicine pack with you.

4. Possible side effects

Diclovol 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 Diclovol Tablets and tell your doctor immediately if you notice:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick).

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclovol Tablets 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).
- 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.
- A persistent sore throat or high temperature.
- An unexpected change in the amount of urine produced and/or its appearance.
- You bruise more easily than usual or have frequent sore throats or infections.

The side effects listed below have also been reported.

Between 1 in 100 and 1 in 10 people have experienced:

- 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.

Between 1 in 10,000 and 1 in 1,000 people have experienced:

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly).
- Inflammation of the stomach, which may cause pain and an upset stomach.
- Drowsiness, tiredness.
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness).
- Skin rash and itching.
- Fluid retention, symptoms of which include swollen ankles.
- Liver function disorders, including hepatitis and jaundice.
- Allergic reactions, including anaphylaxis and shock.
- Asthma, difficulty breathing and lung disorders (alveolitis and pulmonary eosinophilia).
- Kidney problems, which may lead to kidney failure.

Very rare side-effects, reported in less than 1 in 10,000 people include:

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, feeling irritable, depression, anxiety, mental disorders, confusion, hallucinations, malaise, disorientation

and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:

Constipation, a red, swollen tongue, mouth ulcers, taste changes, lower gut disorders (including inflammation of the colon).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), 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, the presence of blood or protein in the urine.

Effects on skin or hair:

Serious skin reactions, including Stevens-Johnson syndrome and Lyell's syndrome, as well as other skin problems, some of which may be made worse by exposure to sunlight. Hair loss or eczema.

Other effects:

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

Tell your doctor immediately if you notice any of the following:

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

If any of the symptoms become troublesome or if you notice anything else not mentioned here, please talk to your doctor. He/she may want to give you a different medicine.

5. How to store Diclovol Tablets

Store below 25°C. Store in the original package to protect from moisture. Keep out of the reach and sight of children.

Do not take Diclovol 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 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. Further Information

What Diclovol Tablets contain

Diclovol 75mg SR Tablets contain 75 mg of the active ingredient, diclofenac sodium. They are modified release tablets, this means they are designed to release the diclofenac sodium more gradually over the day, compared with a standard release tablet. This helps to reduce the number of tablets you may need to take each day.

The tablets also contain the inactive ingredients silicon dioxide, cetyl alcohol, sucrose (powder), povidone, magnesium stearate, hydroxypropylmethylcellulose, polysorbate 80, purified talc, titanium dioxide (E171) and red iron oxide (E172).

What Diclovol Tablets look like and contents of the pack

Diclovol 75 mg SR Tablets are pale pink, triangular, film-coated tablets, embossed D 75 SR on one face and plain on the other face.

They are available in blister packs containing 28, 30, 56 or 60 tablets.

Not all pack sizes may be marketed.

The Marketing Authorisation Holder is

Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR.

The manufacturer of Diclovol Tablets is

Novartis Pharmaceuticals UK Limited, Horsham, West Sussex,
RH12 5AB, England.

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DICLOVOL is a registered trade mark.

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