



PACKAGE LEAFLET: INFORMATION FOR THE USER

DICLO-SR 75
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, pharmacist or nurse.
- 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, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Diclo-SR 75 is and what it is used for
2. What you need to know before you take Diclo-SR 75
3. How to take Diclo-SR 75
4. Possible side effects
5. How to store Diclo-SR 75
6. Contents of the pack and other information

1 What Diclo-SR 75 is and what it is used for

Diclo-SR 75 contains the active substance diclofenac sodium.

Diclofenac sodium is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. Diclo-SR is specially formulated to release the active ingredient slowly, over a long period of time.

Diclo-SR 75 relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:

- Rheumatoid arthritis, osteoarthritis, acute gout (painful inflammation of the joints especially in the feet and hands), ankylosing spondylitis (form of spinal arthritis),
- Backache, 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 dental and minor surgery.

Diclo-SR tablets are not suitable for children.

2. What you need to know before you take Diclo-SR 75

Do not take Diclo-SR 75 if:

- You are allergic to diclofenac sodium, aspirin, ibuprofen or to any other NSAID, or any of the other ingredients of this medicine (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, two or more distinct episodes of 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
- 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
- You have or have had problems with your blood circulation (peripheral arterial disease)
- You are more than six months pregnant

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Diclo-SR 75 if you:

- suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- have kidney or liver problem, or you are an elderly
- have a condition called porphyria (enzyme deficiency affecting the chemicals responsible for blood production in the body)
- 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.
- ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract
- are breast feeding
- have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- have heart problems or if you had a stroke or 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)
- have diabetes
- smoke
- have System Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Diclo-SR 75, as Diclo-SR 75 can sometimes worsen wound healing in your gut after surgery.

Medicines such as Diclo-SR 75 may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

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

If you go into hospital to see a doctor or you have a dental appointment, tell them that you are taking Diclo-SR 75.

If you suffer from any blood or bleeding disorder your doctor may ask you to have regular check ups while taking these tablets.

Children

Diclo-SR 75 tablets are not suitable for children

Other medicines and Diclo-SR 75

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Especially:

- Any other NSAIDs or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- Anticoagulants such as warfarin to prevent blood clots
- Antihypertensives to treat high blood pressure
- Methotrexate and ciclosporin used to treat rheumatoid arthritis and psoriasis
- Corticosteroids used as anti-inflammatory treatments
- Mifepristone (now or at any time in last 12 days)
- Lithium used in the treatment of depression
- Diuretics (water tablets) used to treat blood pressure and water retention
- Digoxin and other medicines used to treat heart problems
- Phenytoin used to treat epilepsy
- Sulphonylureas such as gliclazide or glibenclamide used to treat diabetes
- SSRIs (Selective serotonin reuptake inhibitors) used to treat depression such as fluoxetine and paroxetine
- Anti-platelet agents used to prevent blood clots from forming that can lead to heart attack or stroke eg aspirin, clopidogrel, ticlopidine, dipyridamole
- Tacrolimus used for immunosuppression
- Zidovudine used in the treatment of AIDS and HIV infection
- Trimethoprim used to prevent or treat urinary tract infections
- Colestipol/cholestyramine used to lower cholesterol
- Voriconazole used to treat fungal infections
- Quinolone antibiotics used to treat infections.

Diclo-SR 75 with food and drink

Always take the tablets with plenty of water, preferably with a meal. Try to take them at the same times every day.

Pregnancy, breast-feeding and fertility

- Do not take Diclo-SR 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 Diclo-SR 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, Diclo-SR 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) 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.
- You should advise your doctor or pharmacist if you think you might be pregnant or are up to 6 month pregnant.
- You should talk to your doctor if you are planning to become pregnant or if you have problems becoming pregnant, or if you have problem getting pregnant.
- You should avoid Diclo SR while breast feeding

Driving and using machines

Very occasionally people have reported that Diclo SR 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 effective dose of Diclo SR tablets for the shortest possible time particularly if you are under weight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like diclofenac sodium. 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 Diclo SR tablets 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, Diclo SR 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 Diclo SR tablets.

Diclo-SR 75 contains ethanol and lactose monohydrate

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per dose.

This medicine also contains lactose monohydrate, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information on sodium content

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

3 How to take Diclo-SR 75

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure. The lowest effective dose should be used for the shortest possible time.

Take the tablets with or after food.

Swallow the tablets whole with a glass of water. DO NOT crush or chew the tablets as this will affect the special "slow release" system.

Use in adults and the elderly:

The recommended dose is one tablet once or twice daily, taken whole with plenty of water preferably with food or after food.

Elderly patients are more likely to experience side effects.

Therefore, treatment should be started on the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly.

Use in children:

Diclo-SR 75 is not recommended for use in children.

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ARTWORK DETAIL LABEL

Product	DICLO-SR 75				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	180 x 450 mm	Pack	--		
New Item Code	1051034	Old Item Code	1047924		
Colour Shades	BLACK	No. of Colours	1		
Change Control No.	PC-ODF/2024/441 - Record Number: 427071		Artwork Version	10.0	
Design/Style	Front & Back Printing. To be supplied in folded size of 180 x 225 mm.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				
Caution to the printer:	Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

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 take more Diclo-SR than you should

If you or anyone else, accidentally takes too much Diclo-SR tablets, tell your doctor or go to your nearest hospital casualty department immediately. Take your medicine pack with you so that people can see what you have taken.

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take Diclo-SR

It is important that you do not miss 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 take a double dose to make up for a forgotten tablet. Do not take more than 150 mg in 24 hours. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

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

If you stop taking Diclo-SR

Continue to take the tablets for as long as your doctor tells you to. Talk to your doctor if you have any concerns.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

If you suffer from any of the following side effects, **STOP TAKING** the tablets and seek immediate medical help:

- Sudden and crushing chest pain, (signs of myocardial infarction or heart attack) which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- 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 Diclo-SR and followed by rectal bleeding or bloody diarrhea usually within 24 hours of the onset of abdominal pain
- Stevens-Johnson syndrome (serious illnesses with blistering of the skin, mouth, eyes and genitals)

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

Tell your doctor immediately if you notice the following:

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

The side effects listed below have also been reported.

Common (may affect up to 1 in 10 people):

- Stomach pain, heartburn, nausea, vomiting, diarrhea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood.

Uncommon (may affect up to 1 in 100 people):

- Fast or irregular heart beat (palpitations)
- Chest pain
- Heart disorders, including heart attack or breathlessness, difficulty in 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) dose for a long period of time.

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

- 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 (may affect up to 1 in 10,000 people):

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, 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, taste changes, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease, inflammation of the pancreas.

Effects on the heart, chest or blood:

Hypertension (high blood pressure), inflammation of blood vessels (vasculitis), 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, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Hair loss, itching, facial swelling.

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 Diclo-SR Tablets without any problems.

If any of the side effects becomes serious, or if you notice side effects not listed in this leaflet, please tell your doctor. He/she may want to give you a different medicine.

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 Diclo-SR 75

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Diclo-SR 75 contains

The active substance is diclofenac sodium. Each tablet contains 75mg diclofenac sodium.

The other ingredients are:

- Ethanol (see section 2)
- Lactose Monohydrate (see section 2)
- Magnesium Stearate
- Methylhydroxypropylcellulose
- Microcrystalline cellulose
- Iron oxide red (E172)
- Povidone
- Talc

What Diclo-SR 75 looks like and contents of the pack

Description: Light pink, round convex tablets

Aluminium foil/PVDC/PVC blister strips: Pack sizes 10, 20, 28, 30, 50, 56, 60, 90 and 100 tablets

Not all pack sizes shall be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS,
United Kingdom

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1051034



180 x 450 mm

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Product	DICLO-SR 75				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	180 x 450 mm		Pack	--	
New Item Code	1051034	Old Item Code	1047924		
Colour Shades	BLACK	No. of Colours	1		
Change Control No.	PC-ODF/2024/441 - Record Number: 427071		Artwork Version	10.0	
Design/Style	Front & Back Printing. To be supplied in folded size of 180 x 225 mm.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				
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