

## 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 the group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

Diclo-SR 75 may be used for the relief of pain and swelling in a wide range of conditions including arthritis, musculoskeletal disorders or gout and pain caused by injury or minor surgery.

Diclo-SR 75 is specially formulated to release the active ingredient slowly, over a long period of time.

#### **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 or any of the other ingredients of this medicine (listed in section 6)
- You think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Diclo-SR 75. (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 severe 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 in the last trimester of pregnancy. If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass tarry black stools
- Vomit any blood or dark particles that look like coffee grounds
- **STOP TAKING** the medicine and tell your doctor if you experience: indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

### **Warnings and precautions**

**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 Diclo-SR 75, as Diclo-SR 75 can sometimes worsen wound healing in your gut after surgery.**

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

- Suffer from asthma, or any other breathing condition
- Are an elderly person
- Have System Lupus Erythematosus (SLE or 'Lupus') or other connective tissue disorders
- Suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- Suffer from heart problems
- Suffer from liver or kidney problems
- Have porphyria (enzyme deficiency affecting the chemicals responsible for blood production in the body)
- Suffer from any blood or bleeding disorders
- Are a female attempting to conceive.

**Make sure your doctor knows, before you are given diclofenac:**

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.

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.

### **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:

- Aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs for pain relief (e.g naproxen, diclofenac)
- 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**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Diclofenac does pass into the mother's milk; therefore, breast-feeding should be avoided if taking Diclo-SR 75.

Do not take Diclo-SR 75 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 75 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 75 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. Diclo-SR 75 may make it more difficult to become pregnant.

You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

### **Driving and using machines**

Undesirable effects such as visual disturbances, dizziness, vertigo, drowsiness and tiredness are possible after taking medicines of this type. If you are affected do not drive or operate machinery.

### **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.

**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.

**If you take more Diclo-SR 75 than you should**

If you accidentally take too many Diclo-SR 75 tablets, tell your doctor at once. If you can't do this, go to the nearest casualty department. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

**If you forget to take Diclo-SR 75**

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Diclo-SR 75**

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:

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

**Medicines such as Diclofenac may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.**

**If you experience any of the following stop taking the tablets and contact your doctor immediately:**

- All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eye lids, face or lips, rash, reddening of the skin or itching (especially affecting your whole body)
- Severe painful skin disorder with blisters and peeling skin. You may also have flu-like symptoms such as fever or sore throat (Stevens-Johnson Syndrome)
- Jaundice with symptoms of yellowing of eyes and skin

- Diarrhoea (stop taking Diclo-SR 75 and do not take it again)
- Blood disorders; you may have a persistent sore throat or high temperature, anaemia (feeling tired after exercising, giddiness, looking pale)
- Respiratory problems: including inflammation of the lungs which causes breathlessness, cough and raised temperature and aggravated asthma
- An unexpected change in the amount of urine produced and/or its appearance.

**The side effects listed below have also been reported.**

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

- Nausea, vomiting, 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):**

- Palpitations (fast or irregular heartbeat)
- Chest pain
- Heart disorders, including congestive heart failure.

These symptoms are generally associated in those on long term treatment with a high dose (150mg per day).

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

- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Drowsiness, tiredness
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis
- Raised, itchy rash (Urticaria).

**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 disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, impotence.

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 (pain, feeling sick and being sick).

Effects on the heart, chest or blood:

Hypertension (high blood pressure), inflammation of blood vessels (vasculitis), hypotension (low blood pressure, symptoms of which include faintness, giddiness or light headedness).

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:

Skin rashes which may be made worse by exposure to sunlight. Hair loss, itching, facial swelling.

**Not known (frequency cannot be estimated from the available data):**

Confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances in sensation, injury to the large intestine due to poor blood flow (ischaemic colitis).

### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effect 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, Metro Centre, Tolpits Lane,

Watford, Hertfordshire

WD18 9SS, UK

**This leaflet was last revised in 10/2022**