

PATIENT INFORMATION LEAFLET
DICLO 75 mg 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT DICLO TABLETS ARE AND WHAT THEY ARE USED FOR

Diclo tablets contain the active ingredient diclofenac sodium which is a non-steroidal anti-inflammatory drug (NSAID). It is used for the treatment of severe pain and inflammation of the following conditions:

- osteoarthritis, rheumatoid arthritis, ankylosing spondylitis (characterised by painful and stiff joints), spondylarthritis, psoriatic arthropathy, painful syndrome of the vertebral column, non-articular rheumatism
- acute gout
- frozen shoulder, back pain, tendonitis, bursitis (inflammation of the joints, commonly the knees and elbows)
- bone fractures, sprains, strains, dislocations, dental or other minor surgery
- painful menstruation (period pain).

These tablets are prolonged-release which means they are designed to deliver a dose of a medication over an extended period.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLO TABLETS

Do NOT take Diclo tablets if you:

- are allergic to diclofenac sodium or any of the other ingredients of this medicine (*listed in section 6 and end of Section 2*)
- are allergic to aspirin or any other NSAIDs (e.g. ibuprofen), seen as a red skin rash, wheezing, asthma, face swelling or runny nose. If you are not sure, ask your doctor or pharmacist
- have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen). Reactions may include asthma, chest pain, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice
- 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
- have severe heart failure
- have severe liver or kidney disease
- are in the last 3 months of pregnancy
- you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages in 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).

Warnings and precautions

Talk to your doctor before taking Diclo tablets if you:

- develop serious skin rashes or flaking skin, face swelling, vomiting, abdominal pain, have dark urine/stools in the early part of treatment then **stop taking the tablets and see a doctor immediately**
- have ever had gastrointestinal problems such as stomach ulcer, ulcerative colitis or Crohn's disease, bleeding or black stools. If you have had stomach discomfort or heartburn or any allergic reaction after taking pain relievers or anti-inflammatory medicines in the past or while taking these tablets, **stop taking the tablets and see a doctor immediately**
- are elderly, as you may be more at risk of side effects from NSAIDs. If you notice any gastrointestinal problems, **stop taking the tablets and see a doctor immediately**
- have asthma, seasonal hayfever, nasal polyps (growths in the nasal lining), chronic obstructive pulmonary disease or respiratory tract infections. You may be at risk of an allergic reaction, seen as red skin rash, wheezing, asthma, face swelling or runny nose. If any of these happen, **stop taking the tablets and see a doctor immediately**
- are taking other **pain relievers** or **anti-inflammatory** medicines
- are at risk of being **dehydrated** (e.g. by sickness, diarrhoea, or before or after major surgery)
- have kidney or liver problems or are taking diuretic medicines. You should be monitored carefully
- have heart problems or high blood pressure
- have a **bleeding disorder** or other blood disorders, including a rare liver condition called **hepatic porphyria** or are taking **anticoagulants** such as aspirin or warfarin. You should be monitored carefully
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- if you have Lupus (SLE) or any similar condition
- recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Diclo, as Diclo can sometimes worsen wound healing in your gut after surgery.

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

These tablets should be taken for the shortest possible time. **Your doctor may monitor you with tests to check your blood, liver, kidney and heart function, especially if you are elderly.** If no benefit is seen then the treatment should be stopped.

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 Diclo needs to be discontinued or if the dose needs to be changed.

Other precautions

- Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment.
- If you have heart problems, or have had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol or if you are a smoker), tell your doctor or pharmacist before you take Diclo.
- Diclo may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make it more difficult to detect any other infection. If you feel unwell and need to see a doctor, remember to tell him/her that you are taking Diclo.

Other medicines and Diclo

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

- **lithium** or **SSRI antidepressants** (selective serotonin reuptake inhibitors) such as fluoxetine or paroxetine (used to treat mania and depression); – you may be more prone to gastrointestinal bleeding (*see Section 2 “Take special care”*)

- **digoxin** (medicines used for heart problems)
- **warfarin** medicines used to prevent blood-clotting ("blood thinners" or anticoagulants)
 - you may be at increased risk of bleeding complications
- medicines used to **treat diabetes**, except insulin
- **ciclosporin, tacrolimus** (for patients who have received organ transplants)
- **trimethoprim** (a medicine used to prevent or treat urinary infections)
- **phenytoin** (a medicine to treat epilepsy)
- **colestipol and cholestyramine** (used to lower cholesterol). These medicines can reduce the effect of Diclo. Take Diclo at least 1 hour before or 4 to 6 hours after taking these medicines
- **methotrexate** (used to treat inflammatory conditions and some types of cancer); take care if taking within 24 hours of each other
- Other **anti-inflammatory medicines or pain relievers** such as aspirin or ibuprofen
- **diuretics** (to treat water retention) especially in the elderly. Take plenty of liquid. You will be monitored closely
- **quinolone antibiotics** (for infections)
- **ACE inhibitors or beta-blockers** (for high blood pressure and heart failure)
- **corticosteroids** (for relief of inflammation)
- **potent CYP2C9 inhibitors** such as voriconazole (a medicine used to treat serious fungal infections).

You may be given additional medicine to protect your stomach if you are at risk of gastrointestinal problems.

Pregnancy, breast-feeding and fertility

Do NOT take Diclo tablets if you are in the last 3 months of pregnancy. You should only take Diclo tablets during the first and second trimesters if your doctor considers it necessary. You should not take Diclo tablets if you are trying to become pregnant. As with other anti-inflammatory medicines, the use of diclofenac (the active substance in these tablets), may make it more difficult to become pregnant. This is reversible on stopping the medicine.

Do NOT take Diclo tablets if you are breast-feeding.

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.

Driving and using machines

Usually these tablets have no influence on ability to drive or use machines. However, in rare cases, you may experience vision disorders, dizziness or drowsiness. If you notice such effects, do not drive or use machines.

Diclo tablets contain lactose:

- If you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. HOW TO TAKE DICLO TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure about the dose you should take. These tablets should be taken for the shortest possible time, at the lowest dose to reduce any side effects. Your doctor may monitor you to check your liver, kidney and heart function. If no benefit is seen then the treatment should be stopped. This medicine should only be taken by mouth, after food, with liquid. Do not chew.

The recommended dose is:

- **Adults:** take 1 or 2 tablets daily, with liquid. Do not take more than 2 tablets in one day.
- **Elderly:** you may be more sensitive to the effects of Diclo tablets. Therefore always follow your doctor's instructions carefully and take the minimum number of tablets that provide relief of symptoms. Always drink plenty of fluid. Tell your doctor immediately if you have any side effects (*see Section 4*).
- **Children under 18 years:** this medicine is NOT recommended.

If you take more Diclo tablets than you should

If you have taken more tablets than you should, or someone else has taken the tablets, go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

If you forget to take Diclo Tablets

If you miss a dose, take a tablet as soon as you remember unless it is nearly time for your next tablet. Carry on taking the rest of your tablets at the correct time. Do not take a double dose to make up for a forgotten dose.

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.

Some side effects can be serious. STOP using Diclo tablets and tell your doctor straight away or go to the emergency department at your nearest hospital to seek medical help immediately if you notice any of the following:

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome, or tightness with shortness of breath
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- vomiting of blood, bleeding from the bowel or worsening of ulcerative colitis or Crohn's disease
- sudden slurred speech, facial drooping, weakness, disorientation or speech problems
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath, swelling of the face, lips, tongue or throat, low blood pressure and fainting
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with 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).

The following side effects have also been reported in patients taking Diclo tablets

- 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)

If you experience any of these, tell your doctor straight away.

Other side-effects may occur:

Common (may affect up to 1 in 10 people)

- diarrhoea, nausea, vomiting, indigestion, abdominal pain, flatulence (wind), loss of appetite
- increase in liver enzymes
- headache, dizziness
- skin rash
- vertigo (spinning or swaying sensation).

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

- stomach ulcers or bleeding
- gastritis (inflammation, irritation or swelling of the stomach lining)
- drowsiness, tiredness
- skin rash and itching
- swelling of arms, hands, legs and feet (oedema)
- liver function disorders, including hepatitis and jaundice.

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

- tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, ringing in the ears, sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and memory loss
- constipation, inflammation of the tongue, taste changes, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon)
- palpitations (fast or irregular heart beat)
- skin rashes which may be made worse by exposure to sunlight
- hair loss
- inflammation of blood vessel walls, inflammation of the lungs, congestive heart failure, blood disorders (including anaemia)
- kidney or liver disorders, protein in the urine
- blood in the urine (haematuria)

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DICLO TABLETS

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

Do not store above 25°C. Store in the original package to protect from light and/or moisture.

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

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 75 mg prolonged release tablets contain:

- The **active substance** is diclofenac (as diclofenac sodium – 75 mg per tablet)
- The **other ingredients** are: lactose monohydrate (See end of Section 2 for further information on lactose), hypromellose, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, maize starch, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, red ferric oxide (E172).

What Diclo tablets look like and contents of the pack

Diclo 75 mg tablets are round, flat, pink and white layered tablets available as blister strips in packs of 10 and 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

This leaflet was last revised in August 2019.