DICLORAN® DELAYED RELEASE TABLETS

Diclofenac Sodium (50mg)

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What *Dicloran* is used for?

Dicloran belongs to a group of medicines called "non-steroidal anti-inflammatory drugs" (NSAIDs), which is indicated for relieve of pain, ease inflammation and reduce swelling in conditions affecting the joints, muscles and tendons such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.

How Dicloran works

Dicloran relieves the symptoms of inflammation, such as pain and swelling, by blocking the production of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

Before you use Dicloran

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it

- If you are allergic (hypersensitive) to diclofenac or to any of the other ingredients of DICLORAN listed at the end of this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid, diclofenac or ibuprofen. Reactions may include asthma, runny nose, skin rash, face swelling.
- If you have stomach or intestinal ulcer.
- If you have gastrointestinal bleeding or ruptured bowel, symptoms of which may include blood in your stools or black stools.
- If you suffer from severe kidney or liver disease.
- If you suffer from severe heart failure.

If any of these apply to you, tell your doctor without receiving/taking/using Dicloran. If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or think that you may be pregnant. You should not receive/take/use Dicloran in any form while pregnant unless absolutely necessary.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are receiving/taking/using Dicloran, as it might be harmful for your infant.

Ask your doctor or pharmacist for advice before taking any medicines.

Your doctor will discuss with you the potential risk of receiving/ taking/using Dicloran during pregnancy or breast-feeding.

- Before you start to use it

Take special care

- If you have established disease of the heart or blood vessels (including uncontrolled high blood pressure, heart failure, stroke, or narrowing of the artery, as treatment with Dicloran is generally not recommended.
- If you have established cardiovascular disease (see above) or significant risk factors such as high blood pressure, high levels of fat in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Dicloran, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- It is generally important to take the lowest dose of Dicloran that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had stomach or intestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn's disease).
- If you could be dehydrated (e.g. by sickness, diarrhoea, before or after major surgery).
- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

If any of these apply to you, tell your doctor before you receive/take/use Dicloran in any form.

If, at any time while taking you experience slurring of speech, contact your doctor immediately. Dicloran may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are receiving/taking Dicloran. In very rare cases, Dicloran, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). If you get any of the above described symptoms, tell your doctor straight away.

- Taking other medicines

It is particularly important to tell your doctor if you are taking any of the following medicines have recently taken any other medicines, including medicines obtained without a prescription:

- Lithium (medicines used to treat some types of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- Other anti-inflammatory medicines such as aspirin
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- *Mifepristone:* NSAIDs should not be used for 8-12 days after mifepristone

administration as NSAIDs can reduce the effect of mifepristone.
- "Blood thinners" (medicines used to prevent blood-clotting).
- Medicines used to treat diabetes.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in individuals who have received organ transplants).
- Quinolone antibacterials (medicines used against infections).

How to use Dicloran
Follow your doctor's instructions carefully. Do not exceed the recommended dose.

- How much to use
Do not exceed the recommended dose. Dose to be individually adjusted, lowest effective dose to be given for the shortest duration.
Adults: 100 to 150 mg/day in divided doses (Menstrual cramps : up to 200 mg/day).
Children over 1 year and adolescents**:** 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3mg/kg/day), with a maximum daily dose of 150 mg.

- When to use it
It is recommended to take the tablets before meals or on an empty stomach. It should be swallowed whole with a glass of water or other liquid. Do not divide or chew the tablets.

- How long to use Dicloran
Follow your doctor's instructions exactly. If you take Dicloran for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.
If you have questions about how long to take Dicloran, talk to your doctor or your pharmacist.

- If you forget to use it
If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take the next tablet at the usual time. Do not double the next dose to make up for the one you missed.

- If you use too much (overdose)
Symptoms include headache, nausea, vomiting, pain in the upper middle part of the abdomen, stomach bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in ear , fainting, occasionally and convulsions. In cases of significant poisoning, acute kidney failure and liver damage are possible.

If you have accidentally taken too much Dicloran**,** tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention.

While you are using Dicloran

- Things you must do
Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Dicloran.
Tell your doctor immediately if you become pregnant while taking this medicine.

- Things you must not do
Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.
Do not give Dicloran to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines
Be careful driving or operating machinery until you know how
Dicloran affects you. Dicloran contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

As with all medicines, individuals taking Dicloran can experience side effects, although not everybody gets them.

Stomach and Intestine:
The most commonly observed adverse events are gastrointestinal in nature. Stomach ulcers, ruptured bowel or stomach bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, dark black feces, vomiting of blood, infectious disease of the mouth, colon ulcer and Crohns disease have been reported following administration. Less frequently, gastritis, has been observed.

Hypersensitivity:
Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of a) non-specific allergic reactions and anaphylaxis b) asthma, aggravated asthma, tightening of muscle in lungs or shortness of breath, or c) skin disorders, including rashes of various types, itch, hives, purple or brownish-red spots on the skin, swelling on the surface of skin or mucous membrane and, more rarely redness and peeling of the skin (including severe skin reaction and skin disease that can cause lesion)

Kidney:
Kidney toxicity including swelling in between kidney tubules, excessive protein in urine and kidney failure.

Liver:
Abnormal liver function, hepatitis and jaundice.

Nerve system & special senses:
Visual disturbances, vision disorder , headaches, tingling sensation , reports of the inflammation of the layers of the brain (especially in individuals with existing auto-immune disorders, such as chronic inflammatory condition caused by an autoimmune disease, systemic autoimmune disease.), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation,

depression, confusion, hallucinations, ringing in the ears , sensation of feeling off balance , dizziness, general feeling of being tired , fatigue and drowsiness.

Blood Disorder:
Reduce in white blood cell, red blood cell and platelet count.

Skin Disorder:
Occasional-rashes or breaking out of the skin cases of hair loss, blistering, skin disease that can cause lesion, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Heart and Blood Vessels Disorders:
Uncommon: Heart attack, heart failure, palpitations, chest pain. Swelling with water retention has been reported in association with NSAID treatment.

If you notice any side effects or any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers -> Reporting ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Dicloran*

- *Storage*
  Keep out of the reach and sight of children.
  Store in a dry place, below 25°C and protect from light

- *Disposal*
  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*
  Orange coloured round biconvex enteric coated tablets.
  Each enteric- coated tablet contains Diclofenac Sodium 50.0 mg.

- *Ingredients*
  - Active ingredient
    Diclofenac sodium

  - Inactive ingredients
- Lactose
- Maize Starch BP
- Purified water BP
- Purified Talc BP
- Croscarmellose Sodium NF
- Colloidal Anhydrous Silica BP
- Magnesium Stearate BP
- Acrycoat L30D (Methacrylic acid copolymer dispersion (30%) NF
- Sodium Hydroxide BP
- Diethyl phthalate BP
- Polysorbate 80 BP
- Titanium dioxide BP
- Colour sunset yellow lake (In-house)

- *MAL number:*
  MAL06091360AZ

Manufacturer
Unique Pharmaceutical Laboratories.
(A Division J. B. Chemicals & Pharmaceuticals Limited)
Plot No. 218-219, G.I.D.C. Industrial Area, Panoli: 394 116; Gujarat State, India

Product Registration Holder
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