

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(DICLOLEX-100) Diclofenac sodium 100 mg enteric-coated tablet

Diclofenac sodium

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What DICLOLEX-100 is and what it is used for
2. What you need to know before you take DICLOLEX-100
3. How to take DICLOLEX-100
4. Possible side effects
5. How to store DICLOLEX-100
6. Further information

1. WHAT DICLOLEX-100 IS AND WHAT IT IS USED FOR

Each tablet of DICLOLEX-100 contains Diclofenac sodium 100 mg as the active ingredient. Diclofenac sodium belongs to a group of medicines called Non Steroidal Anti Inflammatory drugs (NSAID's).

DICLOLEX-100 tablets can be used for the treatment of mild to moderate pain including, period pains, back ache, symptomatic relief of sprains, strains and other soft tissue injuries, frozen shoulder, rheumatic pain, sciatica, lumbago, fibrositis, ankylosing spondylitis, osteoarthritis, rheumatoid arthritis, muscular aches and pains, joint swelling and stiffness, acute gout, tendonitis, bursitis, tenosynovitis, dislocations and fractures. DICLOLEX-100 can also be used to treat pain and inflammation associated with minor surgery, including dental surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DICLOLEX-100

Do not take DICLOLEX-100 if;

- you are allergic to diclofenac, aspirin, ibuprofen or any other NSAID, or to any of the inactive ingredients of DICLOLEX-100 Tablets.
- you suffer from, or have ever suffered from, a stomach (gastric) or duodenal (peptic) ulcer or bleeding in the digestive tract.
- you have had stomach or bowel problems after you have taken other NSAIDs.
- you have severe heart, kidney or liver failure.

Cautions before you take DICLOLEX-100

Talk to your doctor or pharmacist before taking **DICLOLEX-100**

- If you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID (Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction).
- If you suffer from, or ever have suffered from stomach or peptic ulcers.
- If you have had stomach or bowel problems after you have taken other NSAIDs.
- If you have severe heart, kidney or liver failure.
- If you are pregnant or breastfeeding.
- If you suffer from any bowel disorders including ulcerative colitis or Crohn's disease.
- If you suffer from any blood or bleeding disorder, if so, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- If you suffer from asthma.
- If you have heart problems, or have had a stroke, or think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol).
- If you suffer from Lupus (SLE) or any similar condition.

If the answer to any of the above questions is YES, tell your doctor or pharmacist because DICLOLEX-100 Tablets might not be suitable for you.

Interactions with other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. DICLOLEX-100 can be affected by or have an effect on other medicines. Talk to your doctor or pharmacist before taking

DICLOLEX-100 if you are taking any of the following medicines:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).
- Cardiac glycosides (for example, digoxin), used to treat heart problems,
- Medicines known as SSRIs used to treat depression.
- Oral steroids (an anti-inflammatory drug).
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors.

Taking DICLOLEX-100 with food and drink

Take this medicine with or after food.

Pregnancy and breast-feeding

As with all medicines it is best to avoid DICLOLEX-100 during pregnancy, or if you are trying to become pregnant unless your doctor has specifically prescribed them for you. However you should not take DICLOLEX-100 tablets during the last 3 months of pregnancy as it may affect the baby's circulation. NSAID's including Diclofenac sodium, should, if possible be avoided whilst breast feeding.

Driving and using machines

Very occasionally people have reported that diclofenac sodium 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.

Important information about some of the ingredients of DICLOLEX-100

Diclofenac Sodium 100 mg contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DICLOLEX-100. Diclofenac Sodium 50 mg contains a colouring agent, which may cause allergic reactions.

3. HOW TO TAKE DICLOLEX-100

Always take DICLOLEX-100 exactly as your health care provider has told you. You should check with your health care provider if you are not sure. Swallow the tablets whole with a drink of water. Do not crush or chew the tablets. It is advisable to take DICLOLEX-100 with food to minimize the risk of gastro-intestinal effects.

The usual doses are:

Adults and children over 12 : 50 mg to 150 mg daily taken in two or three divided doses.

Do not take each dose more frequently than every 6 hours.

Do not take more than the recommended daily dose in 24 hours.

Do not give to children under 12 years of age.

You should take the lowest dose of DICLOLEX-100 for the shortest possible time, particularly if you are underweight or elderly.

If you take more DICLOLEX-100 than you should

If you accidentally take too many tablets, go to your nearest hospital casualty department immediately or contact your doctor. Take your medicine pack with you so that people can see what you have taken. Symptoms of overdose include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding.

If you forget to take DICLOLEX-100

If you forget a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Most people take these tablets without experiencing any problems. However, occasionally some people may get some adverse reactions, although this is rare. Skin rashes and gastro-intestinal disturbances may occur. Gastric or intestinal ulceration with associated bleeding has been reported. DICLOLEX-100 therapy should be discontinued immediately in such cases. Headache, dizziness, oedema, nervousness, pruritus, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (eg. bronchospasm) have occurred.

Blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with DICLOLEX-100 as blood dyscrasias have been reported. DICLOLEX-100 should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants. Patients, who are sensitive to aspirin, generally should not be given DICLOLEX-100. In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

These effects should go away once you stop taking the medicine. If any side effects persist or worsen or you experience any other unusual side effects after taking this medicine, stop taking this medicine and inform your doctor or pharmacist at once.

Use in pregnancy and breast feeding

As with all medicines it is best to avoid DICLOLEX-100 during pregnancy or if you are trying to become pregnant unless your doctor has specifically prescribed them for you. However you should not take DICLOLEX-100 tablets during the last 3 months of pregnancy as it may affect the baby's circulation. NSAID's including diclofenac, should, if possible be avoided whilst breast feeding.

5. HOW TO STORE DICLOLEX-100

Keep out of the reach and sight of children. Do not store above 25 °C. Store in the original carton and away from light. Do not use DICLOLEX-100 after the expiry date which is stated on the carton after 'Exp'. DICLOLEX-100 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.

6. FURTHER INFORMATION

What DICLOLEX-100 contains:

The active pharmaceutical ingredient is Diclofenac sodium.

The other ingredients (excipients) are Colloidal Silicon Dioxide, Magnesium Stearate, Maize Starch, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Methyl Hydroxybenzoate (Methylparaben), Propyl Hydroxybenzoate (Propylparaben), Sodium lauryl sulphate, Lactose and Orange E. C. Pre-Mix.

What DILOLEX-100 looks like and contents of the pack:

DICLOLEX-100 is an orange coloured, circular, biconvex enteric coated tablet with break line on one side and the other side plain. 10 tablets are packed in PVC/aluminum foil blisters and these blisters are packed in printed inner cartons along with an insert. 10 inner cartons are packed in pouches, sealed and packed in outer cartons.

Manufacturer

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