

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine is for you personally and you should 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diclofast tablets are and what they are used for
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1. What Diclofast tablets are and what they are used for

Diclofenac potassium, the active ingredient in Diclofast Tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Diclofast Tablets relieve pain, reduce swelling and ease inflammation in:

- Rheumatoid arthritis, osteoarthritis, acute gout, low back pain, akylosing spondylitis
- Migraine
- Conditions affecting the joints and muscles such as 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 orthopaedic, dental and other minor surgery.

2. Before you take Diclofast tablets

Do not take Diclofast Tablets and talk to your doctor if:
 you are allergic to diclofenac potassium, ibuprofen or any other NSAID, or to any of the other ingredients of Diclofast Tablets. 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
 • 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 had a heart attack or liver failure
 • you have had a heart attack or suffered 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
 Check with your doctor or pharmacist before taking Diclofast tablets if:

- you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- you have kidney or liver problems, or are elderly
- you have a condition called porphyria
- you suffer from any blood or bleeding disorder, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- you have had asthma
- you are breast-feeding
- you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- you have ear problems, or you have 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)
- you have diabetes
- you smoke
- you have Lupus (SLE) or any similar condition
- you have an intolerance to some sugars such as lactose. (Diclofast Tablets contain lactose)

If you are not sure if any of the above applies to you, discuss your treatment with your doctor or pharmacist because Diclofast Tablets are not suitable for everyone.
Taking other medicines:
 Some medicines can interfere with your treatment.
 Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used for some mental problems)
- Methotrexate (used for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclooxygenase-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 betablockers or ACE inhibitors
- Voriconazole (a medicine used to treat fungal infections)
- Phenyletin (a medicine used to treat seizures)
- Colestipol/colestipramine (used to lower cholesterol)

Always tell your doctor about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

Pregnancy and breastfeeding

• Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Diclofast Tablets during the last 3 months of pregnancy as it may affect the baby's circulation.

• If you are trying for a baby, Taking Diclofast Tablets may make it more difficult to conceive.

You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines

Very few people have reported that Diclofast 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 dose of Diclofast for the shortest possible time, particularly if you are underweight or elderly.

• There is a small increased risk of heart attack or stroke when you are taking any medicine like Diclofast. 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.

• 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 a stomach problem 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, Diclofast 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 Diclofast.

3. How to take Diclofast tablets

The doctor will tell you how many Diclofast Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor. Take the tablets with or after food.

Swallow the tablets whole with a drink of water. Do not crush or chew them.

The usual doses are:

Adults:

75 mg to 150 mg daily divided into two or three doses. The number of tablets you take will depend on the strength of the doctor has given you.

For the relief of migraine in adults:

Take 50 mg at the first signs of an attack. If the migraine has not gone after 2 hours, take another 50 mg. You can take further doses at intervals of 4 to 6 hours if necessary, but you must not take more than 200 mg in a day.

Children:

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Diclofast Tablets are not affecting your stomach.

Children over 14:

75 mg to 100 mg daily divided into two or three doses.

Diclofast Tablets are not recommended for children under 14. They are not recommended for the treatment of migraine in children of any age.

The doctor may also advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Diclofast Tablets are not affecting your stomach.

If you take Diclofast tablets you should:

If you, or anyone else, accidentally take too much tablets, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Diclofast tablets

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed.

Do not double up on the next dose to make up for the one missed. Do not take more than 150 mg (three 50 mg tablets) in 24 hours.

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

4. Possible side effects

Diclofast Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minor, but may be serious and may affect your dose for the shortest duration necessary. Some side effects can be serious.

Stop taking Diclofast Tablets and tell your doctor straight away if you notice:

• 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

• Yellow/orange discolouration 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 Diclofast Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor. This side effect has also been reported.

Common side effects (These may affect between 1 in every 10 to 1 in every 100 patients):

• Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite

• Skin rash or spots

• Raised levels of liver enzymes in the blood.

Rare side effects (These may affect between 1 in every 1,000 to 1 in every 10,000 patients):

• 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

• Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)

• Skin rash and itching

• Fluid retention, symptoms of which include swollen ankles

• Liver damage (jaundice, hepatitis and jaundice).

Very rare side effects (These may affect less than 1 in every 10,000 patients):

• Effects on the nervous system:

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, mental disorders, disorientation and loss of memory, fits, headache with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

• Effects on the stomach and digestive system:

• Gastritis or oesophagitis (stomach 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).

• Effects on the heart, chest or blood:

• Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure, or heart attack, blood disorders (including anaemia).

• Effects on the liver or kidneys:

• Kidney or liver disorders including liver failure, presence of blood or protein in the urine.

• Effects on skin and hair:

• Severe skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

• Hair loss:

• Other side effects that have also been reported include:

Inflammation of the pancreas, impotence, facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye.

Medication 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 Diclofast Tablets without any problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Diclofast tablets

- Keep out of the sight and reach of children.

- Store below 30°C.

• Do not use Diclofast after the expiry date which is stated on the packaging. The expiry date refers to the last day of the month. 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.

6. Further Information

What Diclofast film coated tablets contain

Each film coated tablet contains active ingredient Diclofenac Potassium 50 mg.

The excipients are:

Aveled PH 102, Lactose Monohydrate, Maize Starch Plain, P.V.P, XL 10, Magnesium Stearate, Talc Powder, Aerosil 200, Crosscarmellose Sodium, Wt.CAO 1272 Brown.

What does each Diclofast tablet look like and contents of the pack

What does each Diclofast 50 mg film coated tablets are reddish brown coloured, round biconvex film coated tablets, with "KS 57" engraved on one side and other side is plain.

Diclofast 50 mg film coated tablets are available in blister packs of 20 tablets.

This insert was last revised in April 2019

7. Adverse Drug Reaction (ADR) Reporting

For reporting the adverse drug reactions, please refer to the health authorities.

THIS IS A MEDICINE

• Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

• Follow strictly the doctor's prescription, the method of use and instructions of the pharmacist who sold the medicament.

• The doctor and the pharmacist are the experts in the medicines, their benefits and risks.

• Do not by yourself interrupt the period of treatment prescribed for you.

• Do not repeat the same prescription without consulting your doctor.

• Keep all medicaments out of reach of children.

Council of Arab Health Ministers - Union of Arab Pharmacists

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Review Date: DOT(I)-042019-R5-PR4

