

DYFENAC TABLET 50MG

Diclofenac Sodium (50mg)

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What DYFENAC TABLET 50MG is used for

To relieve pain and inflammation of joints, cartilage, bone, spine and following some surgical procedures.

How DYFENAC TABLET 50MG works

It works by reducing the production of prostaglandins (chemicals that cause pain, fever and inflammation). Diclofenac block the enzyme that makes prostaglandins (cyclooxygenase), resulting in lower production of prostaglandins. As a consequence, inflammation, pain and fever are reduced.

Before you use DYFENAC TABLET 50MG

- When you must not use it

- Do not take DYFENAC TABLET 50MG if you have:
- Peptic ulcer
 - Known hypersensitivity to Diclofenac Sodium.
 - Asthma where attacks of asthma, hives, or acute rhinitis are precipitated by Aspirin or by other drugs with prostaglandin-synthesis inhibiting activity.
 - Severe cardiac failure

- Before you start to use it

Tell your doctor if:

- You are pregnant or breast feeding. It should only be used for compelling reasons during pregnancy. You should not take DYFENAC TABLET 50MG during the last 3 months of pregnancy as it may affect the baby's circulation. You should avoid taking Diclofenac Sodium whilst breast

feeding.

- You have bleeding disorders, cardiovascular diseases, peptic ulceration or a history of such ulceration. In the rare instances where peptic ulceration or gastrointestinal bleeding occurs, the drug should be withdrawn. During prolonged treatment, blood counts and monitoring of liver and kidney function are indicated as precautionary measures.
- Severe skin reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis (Lyell's syndrome) have been reported with Diclofenac Sodium. Individuals treated with Diclofenac Sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue Diclofenac Sodium immediately if rash occurs.
- You recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/ taking/using DYFENAC TABLET 50MG, as DYFENAC TABLET 50MG can sometimes worsen wound healing in your gut after surgery.

- Taking other medicines

Care should be taken in individuals treated with any of the following drugs as interactions have been reported in some individuals:

- The anti-hypertensive effect of anti-hypertensive drugs may be reduced.
- The plasma concentrations of digoxin and lithium may be increased by Diclofenac Sodium.
- Increased risk of haemorrhage when non-steroidal anti-inflammatory agents are used in conjunction with anti-coagulants has been reported, as well as increased risk of hypoglycaemic effect when non-steroidal anti-inflammatory agents are used in conjunction with antidiabetic agents.
- The effect on renal prostaglandins may increase cyclosporin toxicity in kidneys.
- Methotrexate plasma levels may be increased and result in increased toxicity, therefore, caution should be exercised if Diclofenac Sodium and methotrexate are administered within 24 hours of each other.
- Diuretics can increase the risk of nephrotoxicity of NSAIDs and there may be reduced diuretic effect.

Serum potassium levels may be raised and should be monitored where there is concomitant treatment with potassium sparing diuretics.

- NSAIDs may exacerbate cardiac failure and reduce kidney function when administered together with medicines for treating heart problems.
- NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
- Concomitant use of two or more NSAIDs (including aspirin) should be avoided.
- There is an increased risk of gastrointestinal bleeding when NSAIDs are administered concomitantly with corticosteroids.
- Individuals taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Seek for your doctor or pharmacist advice if you intended to use DYFENAC TABLET 50MG together with other medication. Besides, you must also inform them about all the medicines you are taking, including those without a prescription.

How to use DYFENAC TABLET 50MG

- How much to use

- Adults: 75 - 150 mg daily in 2 or 3 divided doses.
- In milder cases as well as for long-term therapy, 75 - 100 mg daily is usually sufficient.
- After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.
- As a general recommendation, the dose should be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.
- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label ask your doctor or pharmacist for help.

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- When to use it

DYFENAC TABLET 50MG should be taken according to the time advised by your doctor or pharmacist.

- How long to use it

DYFENAC TABLET 50MG should be taken as your doctor advised you to do so.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- 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 DYFENAC TABLET 50MG

Tell your doctor immediately if you become pregnant while taking this medication.

- 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 DYFENAC TABLET 50MG to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how DYFENAC TABLET 50MG affects

you.

Side effects

Like all medicines, DYFENAC TABLET 50MG can cause side effects, although not everybody gets them.

Possible side effects of DYFENAC TABLET 50MG are gastrointestinal disturbances, peptic ulceration, gastrointestinal bleeding.

Other side-effects include headache, dizziness, nervousness, skin rash, itching, ringing in the ears, swelling, depression, drowsiness, difficulty to sleep, and blurred vision and other eye reactions.

More severe reactions are rare which include hypersensitivity reactions, impairment of liver and kidney functions, lowered white blood cell count and low blood platelet count.

Frequency "not known": Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*).

Storage and Disposal of DYFENAC TABLET 50MG

- Storage

Keep out of reach of children
Do not store above 30°C
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

A light brown, round and biconvex enteric coated tablet

- Ingredients

- Active Ingredient- Diclofenac Sodium

- Inactive Ingredients- Sodium Starch Glycolate, Microcrystalline Cellulose, Corn Starch, Lactose Powder 200 Mesh, Magnesium Stearate, Chloroform Spirit, PVP K90, Aerosil 200, Croscarmellose Sodium.

- MAL number(s):

MAL19913381AZ

Manufacturer & Product Registration Holder

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Date of revision

03/12/2024

Serial Number:

NPRA(R2/1)241203/1383