

# FENADIUM TABLETS 25MG

Diclofenac Sodium (25mg)

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## What Fenadium Tablets is used for

It is used to relief:-

- Inflammatory and degenerative due to arthritis that affects bones and joints.
- Musculoskeletal aches and pains which do not arise from joints.
- Acute attacks of gout.
- Menstrual pain.

## How Fenadium Tablets Works

Fenadium Tablets contains a substance called Diclofenac. It belongs to a group of medicines called non steroidal anti-inflammatory agents (NSAIDs) which reduces fever, pain and inflammation.

## Before you use Fenadium Tablets

### - When you must not use it

Do not use Fenadium Tablets:-

- If you have allergy or hypersensitivity to Diclofenac, Aspirin, other NSAIDs or any other ingredients listed at the end of this leaflet.
- If you have had nasal polyps (growth in the nasal), angioedema (swelling around the eyes and lips and sometimes of the genitals, hands, and feet), bronchospastic (constriction of the airway) and the symptoms become worsen caused by Aspirin or NSAIDs.

### - Before you start to use it

You should check with your doctor:-

- If you have heart problem or stroke.
- If you have high blood pressure.
- Diclofenac may cause severe skin reactions, e.g. toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- If you have or have had ulceration, bleeding and perforation of the stomach and intestinal.
- If you suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- If you have bleeding disorder.
- If you have kidney problem.
- If you are concomitantly administer anticoagulant agents (blood thinning agent).
- Please consult your doctor before start to use Fenadium Tablets if you are pregnant, plan to become pregnant, breastfeeding or intend to breastfeed. Your doctor will have weighed the risks of you taking Fenadium Tablets against the benefits they expect it will have for you.

### - Taking Other Medicines

Some medicines when taken with Fenadium Tablets may interfere with each other. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Lithium, medicine for depression.
- Digoxin, medicine for heart problem.
- Diuretic, Potassium sparing diuretic, water pills.
- Other NSAIDs, medicines for pain.
- Anticoagulants, medicines for blood thinning effect.
- Antidiabetes, medicines for diabetes.
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers.
- Cyclosporin, a medicine used for organ transplant.
- Quinolones, medicines used to treat infection.

## How to use Fenadium Tablets

### - How much to use

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. It is generally given in doses of 25 mg to 50 mg, three times daily.

### - When to use it

Fenadium Tablets is to be taken after meal.

### - How long to use it

It is important to take Fenadium Tablets as long as your doctor prescribes.

### - If you forget to take it

Do not take extra dose to make up for a missed dose. Just take your next dose at usual the time.

### - 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. Taking too many tablets may cause apnea (stop breathing temporary), stomach and intestinal disturbances, pruritus (itchiness), confusion, dizziness and headache.

## While you are using it

### - Things you must do

Take Fenadium Tablets exactly the way as prescribed.

### - Things you must not do

Do not share your medicine with others even if they have the same diagnosis as you.

### - Things to be careful of

Be careful driving or operating machinery until you know Fenadium Tablets affects you. If you experience any side effects, consult your doctor or pharmacist for advice.

## Side Effects

Like all medicines, Fenadium Tablets can cause side effects, although not everybody gets them. The followings have been reported:

- Skin/Hypersensitivity: Occasional rashes or skin eruptions, hair loss, Bullous eruptions (Bullous drug reaction), redness on the skin, Stevens Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and photosensitivity (sensitive to sun light).
- Gastrointestinal: Gastrointestinal disturbances (such as stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting), severe itchiness, sleepiness, dizziness, illness or discomfort, headache, jaundice and bleeding tendency.
- Cardiology: Heart attack, strong pounding of heartbeat, chest pain.
- Haematology: Blood clot.

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

### **Storage and Disposal of Fenadium Tablets**

#### **- Storage**

Store at or below 30°C.

#### **- Disposal**

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

### **Product Description**

#### **- What it looks like**

Round, convex, yellow, enteric-film coated tablets without markings.

#### **- Ingredients**

- Active ingredients

- Diclofenac Sodium

- Inactive ingredients

- Lactose
- Corn Starch
- Magnesium Stearate
- Sodium Starch Glycolate
- Povidone
- Isopropyl Alcohol
- Deionised Water
- Eudragit L100-55
- PEG 6000
- Talcum Powder
- Spectracol Quinoline Yellow
- IPA

#### **- MAL number**

MAL19900395AZ

### **Manufacturer**

Sunward Pharmaceutical Sdn. Bhd.  
No.9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

### **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd.  
No.9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

### **Date of Revision**

14/06/2024

### **Serial Number**

NPRA(R2/1)240606/1283