

# FENADIUM F TABLET

Diclofenac Sodium (50mg)

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## What Fenadium F Tablet is used for

It is used for:-

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis (systemic inflammatory disorder that affects joints); ankylosing spondylitis (chronic inflammatory disease of the skeleton); osteoarthritis (degenerative joint disease) and spondylarthritis (inflammation of the joint).
- Non articular rheumatism (musculoskeletal aches and pains which do not arise from joints).
- Acute attacks of gout.
- Symptomatic treatment for primary dysmenorrhoea (period pain).

## How Fenadium F Tablet Works

Fenadium F Tablet 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 F Tablet

### - When you must not use it

Do not use Fenadium F Tablet:-

- 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 administering anti-coagulant agents (blood thinning agent).
- Please consult your doctor before start to use Fenadium F Tablet if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Fenadium F Tablet against the benefits they expect it will have for you.

### - Taking Other Medicines

Some medicines when taken with Fenadium F Tablet 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 you doctor or pharmacist

- 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 F Tablet

### - 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 F Tablet is to be taken after meal.

### - How long to use it

It is important to take Fenadium F Tablet 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 F Tablet 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 F Tablet affects you. If you experience any side effects, consult your doctor or pharmacist for advice.

## Side Effects

Dermatological Occasional: Rashes or skin eruptions may occur. Severe skin reaction such as of hair loss, bullous eruptions (Bullous drug reaction), ery-thema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and photosensitivity reactions have been reported. Others include gastrointestinal disturbances (stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting), severe itchiness, sleepiness, dizziness, illness or discomfort, headache, jaundice and bleeding tendency.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting).

## **Storage and Disposal of Fenadium F Tablet**

### - Storage

Store at temperature 25°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

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

### - Ingredients

- Active Ingredients

- Diclofenac Sodium

- Inactive ingredients

- Lactose
- Corn Starch
- Sodium Starch Glycolate
- PVP-K30
- Magnesium Stearate
- Isopropyl Alcohol
- Eudragit L 100-55
- PEG-6000
- Talcum
- Eurolake Cochincal Red Colour 36%
- Lake Green No.2
- Deionized Water

### - MAL number

MAL19900396AZ

## **Manufacturer**

Sunward Pharmaceutical Sdn. Bhd.  
9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

## **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd.  
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## **Date of revision**

24/03/2016

## **Serial Number**

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