# **FAMODINE TABLET**

Famotidine (20mg)

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#### What Famodine is used for

This medicine is used to treat:

- Duodenal ulcer
- Benign gastric ulcer
- Zollinger-Ellison syndrome (excess acid production in the stomach caused by growth in the pancreas)
- Prevention of relapses of duodenal ulceration
  - Short term (no more than 12 weeks) symptomatic relief of gastroesophageal reflux not responsive to conservative measures
  - Healing of oesophageal erosion or ulceration associated with gastroesophageal reflux disease.
  - Prevention of relapses of symptoms and erosions or ulcerations
- Gastroesophageal reflux disease (backward flow of stomach acid into the esophagus)

#### **How Famodine works**

Famodine contains the active ingredient famotidine. Famotidine belongs to a group of medicines called H2 antagonists or H2 blockers.

It works by decreasing the amount of acid made by the stomach. This helps to reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

## Before you use Famodine

### - When you must not take it

Do not take this medicine if you have an allergy to:

- Famotidine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal. If you are not sure whether you should start taking this medicine, talk to your doctor.

### - Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Your doctor may decide that you need some tests to rule out gastric tumour because famotidine also alleviates the symptoms of cancer and could cause delay in diagnosing it.

Usage in children: Safety and effectiveness of Famotidine in children have not been established.

As elderly people are more likely to have decreased clearance of famotidine, doctor may adjust the dose accordingly and monitor the kidney function.

Use in Lactation: Famotidine is detectable in human milk. Nursing mothers should either stop this medicine or stop nursing.

Famotidine is not recommended for use in pregnancy. Before a decision is made to use Famotidine during pregnancy, doctor will weigh the potential benefits from the medicines against the possible risks involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Famodine.

#### - Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Famodine has not been shown to interfere with other medicines.

#### How to use Famodine

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

# - How much to use

The dosage of Famodine depends on the condition it is being used to treat.

Duodenal and Benign Gastric

Take 40mg daily taken at night for 4 to 8 weeks.

Zollinger-Ellison syndrome Treatment should be started on a dose of 20mg every six hours. Dosage should be adjusted to individual needs.

Gastroesophageal reflux disease

The usual dosage for the treatment and maintenance of reflux disease is 20mg to be taken twice a day.

In people with moderate to severe kidney insufficiency, the dose of famotidine may be reduced to half the recommended dose or the dosing interval may be prolonged to 36 – 48 hours as indicated by the person clinical response.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

#### - When to use it

Famodine can be taken with or without food.

If you are taking one dose a day, take the medicines at night.

If you are taking two doses a day, take medicines in the morning and one at night.

Take your medicines at about the same time each day.

This will help you remember when to take the medicines.

# - How long to use it

Do not stop taking Famodine, even if you feel better after a few days, unless advised by your doctor.

The ulcer may come back if you stop treatment earlier.

The duration of treatment with Famodine depends on the condition it is being used to treat.

# - If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

# - <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Famodine.

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

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Famodine.

If you become pregnant while taking this medicine, tell your doctor immediately.

#### Things you must not do

Do not lower the dosage without checking with your doctor.

Do not take Famodine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

# Things to be careful of

Be careful driving or operating machinery until you know how Famodine affects you.

#### Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- \* headache
- \* dizziness
- \* constipation
- \* diarrhoea.

These are generally mild side effects.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my

(Consumers  $\rightarrow$  Reporting).

# Storage and disposal of Famodine

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C. Protect from light.

Do not store Famodine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### - Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## **Product Description**

### - What it looks like

Famodine Tablet 20mg: Capsule-shaped tablet, yellow, 11mm, scored on one side and marked 'D 861' on the other side.

#### - Ingredients

Active ingredient

• Famotidine

Inactive ingredients

- promigel
- magnesium stearate
- aerosil
- cornstarch
- lactose
- polyvinylpyrrolidone (PVP)
- quinoline yellow

# - MAL number

Famodine Tablet 20mg: MAL19900668A

#### Manufacturer

Duopharma (M) Sdn. Bhd. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

# **Product Registration Holder**

Duopharma (M) Sdn Bhd. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

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