

## Package leaflet: Information for the user

### Famotidine Clonmel Healthcare 20 mg film-coated tablets Famotidine Clonmel Healthcare 40 mg film-coated tablets

famotidine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Famotidine Clonmel Healthcare is and what it is used for
2. What you need to know before you take Famotidine Clonmel Healthcare
3. How to take Famotidine Clonmel Healthcare
4. Possible side effects
5. How to store Famotidine Clonmel Healthcare
6. Contents of the pack and other information

#### **1. What Famotidine Clonmel Healthcare is and what it is used for**

Famotidine Clonmel Healthcare works by reducing the amount of acid produced in the stomach. It is used to treat certain conditions caused by too much acid produced in the stomach. It is a gastrointestinal medicine that belongs to a group of medicine called Histamine H<sub>2</sub>-receptor antagonists.

Famotidine Clonmel Healthcare is used in adults for the treatment of

- prevention of recurrent duodenal ulcers (only with Famotidine Clonmel Healthcare 20 mg)
- duodenal ulcer
- benign gastric ulcer
- treatment of Zollinger-Ellison syndrome. This is a condition caused by abnormal production of the hormone gastrin that causes an overproduction of stomach acid
- symptoms of reflux disease (mild reflux oesophagitis), such as heartburn (Famotidine Clonmel Healthcare 20 mg)
- mild to moderate inflammation of the oesophagus (food pipe) (Famotidine Clonmel Healthcare 40 mg)

#### **2. What you need to know before you take Famotidine Clonmel Healthcare**

##### **DO NOT take Famotidine Clonmel Healthcare**

- if you are allergic to famotidine, peanut, or soya or any of the other ingredients of this medicine (listed in section 6). If symptoms of hypersensitivity develop, Famotidine Clonmel Healthcare should be discontinued.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Famotidine Clonmel Healthcare.

- **Tell your doctor immediately** if you notice any of the following symptoms:
  - an unintentional loss of weight
  - repeated vomiting

- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools

Your doctor may decide that you need some tests to rule out malignant disease because famotidine also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

- you should not use Famotidine Clonmel Healthcare if you suffer from minor gastrointestinal complaints. Please ask your doctor.
- if you suffer from duodenal ulcers and benign gastric ulcers your doctor may decide that these have been caused by a bacterial infection with *H.pylori*. If this is the case you should undergo a special therapy under direction by the doctor to eliminate these bacteria.
- if you suffer from kidney (renal) impairment. Your doctor may prescribe you a lower dose of Famotidine Clonmel Healthcare (see 3. "How to take Famotidine Clonmel Healthcare").

If you take a high dose for a long time your doctor may carry out blood tests to check your blood cells and liver function.

### Children

No sufficient experience has been gained on the safety and efficacy of famotidine in children. Therefore, children should not be treated with famotidine.

### **Other medicines and Famotidine Clonmel Healthcare**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please contact your doctor if you take any of the medicines mentioned below:

### You should not take Famotidine Clonmel Healthcare

- if you take the substance probenecid (a medicine to treat gout) at the same time, because probenecid can delay the elimination of famotidine.
- in combination with atazanavir, ritonavir and tenofovir (medicines used to treat HIV infection)

### The effect of Famotidine Clonmel Healthcare can be reduced by:

- medicines to neutralize the stomach acid (antacids). As the effect of Famotidine Clonmel Healthcare will be reduced, you should take Famotidine Clonmel Healthcare at least 1-2 hours before taking an antacid.
- sucralfate (medicine to treat ulcers). As a rule you should not take sucralfate within 2 hours of Famotidine Clonmel Healthcare.

### Famotidine Clonmel Healthcare may reduce the effect of:

- ketoconazole or itraconazole (medicines to treat fungal infections). You should take ketoconazole 2 hours before taking Famotidine Clonmel Healthcare.
- atazanavir with ritonavir (medicines taken for HIV infection). Please ask your doctor.
- calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis.
- posaconazole oral suspension (a drinkable medicine used to prevent and treat some fungal infections).
- dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Pregnancy

Famotidine Clonmel Healthcare can be used during pregnancy if it is clearly necessary.

#### Breast-feeding

Famotidine is excreted in breast milk only in small amounts. Therefore, Famotidine Clonmel Healthcare can be used during breast-feeding.

#### **Driving and using machines**

Famotidine Clonmel Healthcare may cause side effects such as dizziness, headache and drowsiness which may impair your ability to react. You should be aware of this if you are driving or operating machinery.

#### **Famotidine Clonmel Healthcare contains soya lecithin**

If you are allergic to peanut or soya, do not use this medicine.

### **3. How to take Famotidine Clonmel Healthcare**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **Method of administration:**

Famotidine Clonmel Healthcare should be swallowed whole with some liquid. It does not need to be taken at mealtimes.

**The recommended dose** depends on the severity of your disease and the dosage of previous medications. Your doctor will decide how much you should take.

Recommended doses are given below:

#### Adults:

#### ***Prevention of recurrent duodenal ulcers (only with Famotidine Clonmel Healthcare 20 mg)***

20 mg of famotidine in the evening.

The recommended maintenance dose of 20 mg has been continued effectively in clinical studies of 12 months duration.

#### ***Duodenal ulcers and benign gastric ulcers***

40 mg of famotidine before going to sleep.

The therapy should last for 4 to 8 weeks. However, this period may be shortened if your doctor finds that the ulcer has healed (e.g. by an endoscopic examination). If the examination does not show that the ulcer has healed then treatment should be continued for another 4 weeks.

#### ***Zollinger-Ellison syndrome***

Providing there has not been previous therapy, the treatment starts with 20 mg of famotidine every 6 hours.

Depending on the acid secretion and your clinical response, your doctor may increase the dose as treatment continues until the desired acid levels have been reached. If treatment with a daily dosage of up to 800 mg doesn't work, your doctor may consider an alternative treatment to regulate acid secretion.

If you have previously undergone a treatment with similar medicines (e.g. other Histamine H<sub>2</sub> receptor antagonists) it is possible to start the treatment with Famotidine Clonmel Healthcare at a higher dosage than the initial dosage that is usually recommended. Ask your doctor about the right dosage.

Treatment should be continued for as long as necessary.

#### ***Treatment of symptoms of reflux disease (e.g. heartburn) (only with Famotidine Clonmel Healthcare)***

**Healthcare 20 mg)**

20 mg of famotidine twice a day.

Treatment usually lasts for 6 weeks, but your doctor may extend your treatment for another 6 weeks.

**Treatment of mild to moderate inflammation of the oesophagus (food pipe) (only with Famotidine Clonmel Healthcare 40 mg)**

40 mg of famotidine twice a day.

Treatment usually lasts for 6 weeks, but your doctor may extend your treatment for another 6 weeks if treatment does not result in healing.

Patients with impaired kidney (renal) function

If you suffer from impaired renal function your doctor may reduce the daily dose to 50%. Dialysis patients should also take dosages that are reduced to 50%. Famotidine Clonmel Healthcare should be administered at the end of dialysis or thereafter since some of the active ingredient is removed via dialysis.

Children

Famotidine Clonmel Healthcare must not be taken by children.

**If you take more Famotidine Clonmel Healthcare than you should**

Contact your doctor or the nearest hospital immediately. Your doctor will make efforts to inhibit absorption and relieve symptoms. Up to now there are no reports of overdosing with the active ingredient famotidine.

**If you forget to take Famotidine Clonmel Healthcare**

If you forget to take a dose, take one as soon as you remember and continue as before. Do not take a double dose to make up for a forgotten dose. If you are concerned about missing your dose ask your doctor for advice.

**If you stop taking Famotidine Clonmel Healthcare**

Talk to your doctor if you wish to stop taking Famotidine Clonmel Healthcare.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking the medicine and contact your doctor immediately or go to the casualty department at your nearest hospital:

**Rare side-effects (may affect up to 1 in 1 000 people)**

- serious allergic/hypersensitivity reactions which causes difficulty in breathing or dizziness (anaphylaxis), swelling of the face or throat (angioneurotic oedema), difficulty in breathing or wheezing (bronchospasm)

**Not known (frequency cannot be estimated from the available data)**

- severe skin rash with blistering (Stevens-Johnson syndrome / toxic epidermal necrolysis)

**The following side effects have been reported:**

**Common side-effects (may affect up to 1 in 10 people):**

- headache
- dizziness
- constipation (obstipation)

- diarrhoea

***Uncommon side-effects (may affect up to 1 in 100 people):***

- dry mouth
- nausea, vomiting
- gastrointestinal complaints
- excessive internal gas (flatulence)
- loss of appetite
- rash, itching (pruritus)
- tiredness (fatigue)

***Rare side-effects (may affect up to 1 in 1 000 people):***

- yellowing of the skin or the whites of the eyes caused by blockade of bile flow (jaundice caused by intrahepatic cholestasis)
- hives (urticaria)
- joint pain (arthralgia)
- increase in laboratory values (transaminases, gamma GT, alkaline phosphatase, bilirubin)

***Very rare side-effects (may affect up to 1 in 10 000 people):***

- changes in the blood: a fall in the number of all types of blood cells (pancytopenia) or a fall in the number white blood cells (leukopenia, agranulocytosis) or blood platelets (thrombocytopenia), which can cause e.g. weakness, fatigue, sudden fever, sore throat, bruising or nose bleed.
- reversible psychological disturbances (e.g. hallucinations, disorientation, confusion, anxiety, agitation, depression)
- tingling or numbness in the hand or feet (paraesthesia)
- drowsiness
- sleeplessness
- epileptic seizures (grand mal)
- hair loss (alopecia)
- muscle cramps
- impotence, reduced libido
- feelings of tightness in the chest

***Not known (frequency cannot be estimated from the available data)***

- inflammation of the liver (hepatitis)

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland: HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie)

Malta: ADR Reporting, Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Famotidine Clonmel Healthcare**

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month,

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist

how to throw away medicines you no longer use. These measures will help protect the environment

## 6. Contents of the pack and other information

### What Famotidine Clonmel Healthcare contains

The active substance is famotidine.

*Famotidine Clonmel Healthcare 20 mg film-coated tablets:*

Each film-coated tablet contains 20 mg of famotidine.

*Famotidine Clonmel Healthcare 40 mg film-coated tablets:*

Each film-coated tablet contains 40 mg of famotidine.

### The other ingredients are:

Tablet core: Silica, colloidal anhydrous (E 551), cellulose, microcrystalline (E 460 (i)), starch, pregelatinized, talc (E 553 b), silica, colloidal anhydrous (E 551), magnesium stearate (E 470b)  
Tablet coat: Polyvinyl alcohol-Partially hydrolysed (E1203), talc (E 553 b), titanium dioxide (E 171), macrogol, lecithin (soya) (E322), iron oxide yellow (E172), iron oxide red (E172).

### What Famotidine Clonmel Healthcare looks like and contents of the pack

Famotidine Clonmel Healthcare 20 mg

Yellow coloured, round, biconvex film-coated tablets debossed with “2V” on one side. Approximately 6 mm in diameter.

Famotidine Clonmel Healthcare 40 mg

Brown coloured, round, biconvex film-coated tablets debossed with “4V” on one side. Approximately 8 mm in diameter.

oPA/Alu/PVC//Alu or PVC/Alu blisters

Famotidine Clonmel Healthcare 20 mg is available in blisters containing 10, 20, 28, 30, 50, 60 or 100 film-coated tablets.

Famotidine Clonmel Healthcare 40 mg are available in blisters containing 10, 20, 28, 30, 50 or 100 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

#### Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

Centrafarm Services B.V., Van de Reijtstraat 31 E, 4814NE Breda, Netherlands

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands: Famotidine Centrafarm 20 mg and 40 mg, filmomhulde tabletten

Austria: Famotidin Stada 20 mg and 40 mg Filmtabletten

France: FAMOTIDINE EG LABO 20 mg and 40 mg, comprimé pelliculé

Germany: Famotidin STADA 20 and 40 mg Filmtabletten

Ireland: Famotidine Clonmel Healthcare 20 mg and 40 mg film-coated tablets

Italy: FAMOTIDINA EG STADA

Malta: Famotidine Clonmel Healthcare 20 mg and 40 mg film-coated tablets  
Spain: Famotidina STADA 20 mg and 40 mg comprimidos recubiertos con película

**This leaflet was last revised in October 2025.**