FAMOTIDINE 20MG TABLETS
PL 32019/0033
&
FAMOTIDINE 40MG TABLETS
PL 32019/0034

(FAMOTIDINE)

UKPAR

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FAMOTIDINE 20MG & 40MG TABLETS
PL 32019/0033-0034

(FAMOTIDINE)

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Roger Oakes Limited Marketing Authorisations (licences) for the medicinal products Famotidine 20mg Tablets (PL 32019/0033) and Famotidine 40mg Tablets (PL 32019/0034) on 6th July 2009. These are prescription-only medicines (POM).

The active ingredient, famotidine, is one of a group of medicines known as 'H2-receptor antagonists' which work by reducing the amount of acid your stomach produces.

Famotidine Tablets are used to treat the following:

- Stomach ulcers (gastric / duodenal ulcers)
- Irritation and inflammation caused by stomach acid leaking into the gullet (reflux oesophagitis)
- Zollinger-Ellison Syndrome (a rare disorder that involves recurrent ulcers and tumours in the stomach and intestines)

These applications are duplicates of previously granted applications for Famotidine 20mg Tablets and Famotidine 40mg Tablets (PL 11311/0226-0227), held by Tillomed Laboratories Limited, and authorised in the UK on 13th November 2003. The test and reference products are identical.

No new or unexpected safety concerns arose from these simple applications and it was therefore judged that the benefits of taking Famotidine 20mg and 40mg Tablets outweigh the risks; hence Marketing Authorisations have been granted.

FAMOTIDINE 20MG & 40MG TABLETS
PL 32019/0033-0034

(FAMOTIDINE)

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Roger Oakes Limited Marketing Authorisations for the medicinal products Famotidine 20mg Tablets (PL 32019/0033) and Famotidine 40mg Tablets (PL 32019/0034) on 6th July 2009. The products are prescription-only medicines.

These applications were submitted as simple abridged 'informed consent' applications according to article 10c of Directive 2001/83/EC (as amended), cross-referring to the Marketing Authorisations Famotidine 20mg Tablets and Famotidine 40mg Tablets (PL 11311/0226-0227), granted to Tillomed Laboratories Limited on 13th November 2003 through the Mutual Recognition Procedure.

Famotidine Tablets are indicated for the following:

- Duodenal and benign gastric ulcers which have been confirmed by radiological or endoscopic examination
- Zollinger-Ellison syndrome
- Reflux oesophagitis confirmed by endoscopy, including curative treatment of erosion or ulcer associated with reflux oesophagitis.

Famotidine is an effective competitive H_2 receptor antagonist, the effect of which is particularly clearly concentrated on H_2 receptors. It reduces the concentration and amount of acid and pepsin of the gastric juices in the basal and stimulated secretion.

The effect of oral administration of famotidine is rapid. The effect of famotidine is long lasting when recommended doses are used, and it is effective with relatively low concentrations in the blood. The duration of effect, plasma concentration and secretion in the urine are dose dependent.

Oral administration of famotidine leads to the antacid effect starting within an hour of administration. The peak effect is dose dependent and it is achieved within 1-3 hours of administration.

No new data were submitted nor was it necessary for these simple applications, as the data are identical to that of the previously granted cross-reference products. As the cross-reference products were granted prior to the introduction of current legislation, no PAR was generated for them.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBERS:	PL 32019/0033 & 0034
PROPRIETARY NAME:	Famotidine 20mg & 40mg Tablets
ACTIVE INGREDIENTS:	Famotidine
COMPANY NAME:	Roger Oakes Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	POM

1. INTRODUCTION

These are simple abridged applications, submitted under Article 10c of Directive 2001/83/EC (as amended) for Famotidine 20mg & 40mg Tablets. The proposed MA holder is Roger Oakes Limited.

The reference products are Famotidine 20mg and 40mg Tablets (PL 11311/0226-0227), granted to Tillomed Laboratories Limited on 13th November 2003. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the products are Famotidine 20mg Tablets and Famotidine 40mg Tablets. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each film-coated tablet contains 20mg or 40mg of the active ingredient famotidine. The tablets are marketed in PVC - aluminium blister strips, which are packaged with the Patient Information Leaflet (PIL) into cardboard outer cartons in pack sizes of 5, 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 90, 98, and 100.

The approved shelf-life (36 months) and storage conditions ('Do not store above 25°C' and 'Store in the original package') are consistent with the details registered for the cross-reference product.

2.3 Legal status

The products are available by supply through pharmacies, subject to a medical prescription.

2.4 Marketing authorisation holder / Contact Persons/Company

The proposed Marketing Authorisation holder is 'Roger Oakes Limited, Allstoe House, Church Lane, Greetham, Rutland LE15 7NF'.

The QP responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8 Finished product / shelf-life specification

The proposed finished product specifications are in line with the details registered for the cross-reference products.

2.9 Drug substance specification

The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

2.10 TSE Compliance

The magnesium stearate is of vegetable origin. The only excipient used that contains material of animal or human origin is lactose monohydrate. The applicant has provided a declaration that milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts were provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearance of the products (White, oblong, biconvex tablet, scored on one side) is consistent with that of the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The approved SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

The patient information leaflet has been prepared in the user tested format and in line with the details registered for the cross-reference products. The approved PIL is satisfactory.

Cartons

Colour mock-ups of the labelling have been provided and are satisfactory. The approved artwork is comparable to the artwork registered for the cross-reference products and complies with statutory requirements. In line with current legislation the applicant has included the name of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The grounds for these applications are considered adequate. Marketing Authorisations were therefore granted.

PRECLINICAL ASSESSMENT

These applications were submitted as simple abridged applications according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with these applications and none are required for applications of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

These applications were submitted as simple abridged applications according to article 10c of Directive 2001/83/EC (as amended).

As these are duplicate applications for PLs 11311/0226 and 0227, no new clinical data have been supplied with the applications, and none are required for applications of this type. A clinical expert report has been written by a suitably qualified person and is satisfactory.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with that previously assessed for the cross-reference products and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Medicinal products containing famotidine have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

These applications are identical to the cross-reference products Famotidine 20mg Tablets and Famotidine 40mg Tablets (PL 11311/0226-0227, Tillomed Laboratories Limited).

No new or unexpected safety concerns arise from these applications.

PRODUCT LITERATURE

The approved SmPCs, PIL and labelling are satisfactory and consistent with that for the cross-reference products.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The testing shows that patients/users are able to act upon the information that the leaflet contains.

The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging and sufficient space has been included for a standard UK pharmacy dispensing label. The Marketing Authorisation Holder (MAH) has stated that not all pack sizes may be marketed. However, they have committed to submitting mock-ups for all packaging for assessment before those pack sizes are commercially marketed.

RISK BENEFIT ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. Extensive clinical experience with famotidine is considered to have demonstrated the therapeutic value of the active substance. The risk: benefit is, therefore, considered to be positive.

FAMOTIDINE 20MG & 40MG TABLETS
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STEPS TAKEN FOR ASSESMENT

1 The MHRA received the marketing authorisation applications on 14th November 2008

2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 1st December 2008

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 19th December 2008

4 The applicant responded to the MHRA's request, providing further information for the quality sections on 1st May 2009

5 The applications were determined on 3rd July 2009 and granted on 6th July 2009

FAMOTIDINE 20MG & 40MG TABLETS
PL 32019/0033-0034

(FAMOTIDINE)

STEPS TAKEN AFTER AUTHORISATION

Not applicable

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Famotidine 20mg Tablets (PL 32019/0033) and Famotidine 40mg Tablets (PL 32019/0034) is as follows – Differences are indicated by blue text with yellow highlight:

1 NAME OF THE MEDICINAL PRODUCT

Famotidine 20mg Tablets / Famotidine 40mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains famotidine 20 mg / 40 mg.

Also contains lactose

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

White, oblong, biconvex tablet, scored on one side

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Duodenal and benign gastric ulcers which have been confirmed by radiological or endoscopic examination.

Zollinger-Ellison syndrome

Reflux oesophagitis confirmed by endoscopy, including curative treatment of erosion or ulcer associated with reflux oesophagitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Dosage directions for individual and daily doses

Duodenal ulcer.

Initiation of treatment: The recommended dose is 40 mg of famotidine per day at bedtime. The treatment should be continued for 4-8 weeks, but it may be discontinued even earlier if it is found by endoscopic examination that the ulcer has healed. In most cases the ulcer will heal with this treatment within four weeks. Treatment should be continued for another four weeks in patients whose ulcer has not healed completely within four weeks.

Maintenance treatment: In prophylactic treatment of recurrent ulcer it is recommended that famotidine therapy be continued with a dose of 20 mg per day at bedtime.

Non-malignant gastric ulcer.

The recommended dose is 40 mg per day at bedtime. The treatment is continued for 4-8 weeks, but a shorter course of treatment is adequate if an endoscopic examination shows that the ulcer is healed.

Zollinger-Ellison syndrome.

If the patient has not previously received drugs to reduce the secretion of acid, the treatment is introduced by giving 20 mg of famotidine every 6 hours. The dosage should be adjusted according to the patient's needs and it should be continued as long as it is clinically indicated. Daily doses up to 800 mg have been administered without any significant undesirable effects or tachyphylaxis. If the patient has received another H_2 blocking agent, famotidine therapy can be introduced in a larger dose than otherwise recommended. The size of the initial dose is dependent on the severity of the condition and on the size of doses of H_2 blocking agents received until that time.

Reflux oesophagitis.

The recommended dose for the relief of symptoms of reflux oesophagitis is 20 mg of famotidine twice daily. Doses should be continued for as long as indicated.

The recommended dose for the treatment of erosion or ulcer associated with reflux oesophagitis is 40 mg of famotidine twice daily. The recommended treatment length is 6-8 weeks.

Maintenance treatment:

If long-term management of reflux oesophagitis by famotidine is considered relevant, the recommended dose is 20 mg twice daily.

At present, this prophylactic treatment is not recommended to be extended beyond six months.

Renal impairment:

Famotidine is primarily eliminated via the kidneys. For patients with impaired renal function in whom creatinine clearance is less than 30ml/min, the daily dose of famotidine should be reduced by 50%. Caution is advised in patients with renal impairment. Dialysis patients should also take doses that are reduced by 50%. Famotidine tablets should be administered at the end of dialysis or later since some of the active ingredient is removed by dialysis.

Hepatic impairment

In patients with cirrhosis of the liver, the plasma concentration and elimination of famotidine in the urine were the same as that of healthy volunteers. Reduction of the dose is therefore not necessary in these patients.

The elderly.

When famotidine was administered to elderly patients in clinical studies the undesirable effects associated with the drug were not found to increase nor were they found to be different from those exhibited in younger patients. Adjustment of dose based on age is therefore not necessary.

Children

Not recommended.

Mode of administration

The tablets should be taken with some liquid. They can be divided, but they must not be crushed or chewed.

4.3 CONTRAINDICATIONS

Hypersensitivity to famotidine or any of the other excipients.

For administration to breast-feeding women: see section 4.6

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Since cross sensitivity has been observed among H_2-receptor antagonists, famotidine should not be administered to patients with a history of hypersensitivity to other drugs in this class.

Gastric carcinoma.

Before starting treatment of gastric ulcer with famotidine, the possibility of malignant gastric tumour should be excluded. The symptomatic response of a gastric tumour to famotidine therapy does not exclude the possible existence of a malignant tumour.

Do not administer famotidine tablets in cases of minor gastro-intestinal complaints.

In patients with duodenal ulcers and benign gastric ulcers the H. Pylori status should be determined. Wherever possible, patients with H. Pylori should undergo eradication therapy to eliminate the bacteria.

Renal insufficiency.

Since famotidine is secreted mainly via the kidneys, caution should be exercised when treating patients with renal insufficiency. A reduction in the daily dose should be considered if creatinine clearance falls below 30 ml/min (see section 4.2 Posology and Method of administration).

This medicine contains 1.99 mg / 3.19 mg of lactose per tablet. Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

During concomitant use of drugs where the absorption of the drug is affected by the amount of gastric juice, a possible effect on the absorption should be taken into consideration. The absorption of ketoconazole and itraconazole could be reduced. Ketoconazole should be given two hours before famotidine administration.

Probenecid inhibits renal tubular secretion of famotidine, and has been shown to cause a 50% increase in plasma levels of famotidine. Therefore, concomitant use of probenecid and famotidine should be avoided.

Concomitant use of famotidine and antacids could reduce the famotidine uptake and cause lower plasma levels of famotidine. Therefore, famotidine should be administered 1-2 hours before antacids.

Concomitant use of sucralfate inhibits absorption of famotidine. Therefore, sucralfate should not be administered within 2 hours after famotidine.

4.6 PREGNANCY AND LACTATION

Use during pregnancy:
Data on a limited number of exposed pregnancies indicate no adverse effects of famotidine on pregnancy or on the health of the foetus / newborn child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal / foetal development, parturition or postnatal development (see section 5.3). Caution should be exercised when prescribing to pregnant woman.

Use during lactation: Famotidine is excreted in breast milk. Breast-feeding mothers should either stop using this drug or stop breast-feeding, since there is a possibility of famotidine affecting the infant's gastric acid secretion.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known

4.8 UNDESIRABLE EFFECTS

Blood and the lymphatic system disorders

Very rare (< 1/10,000):

Thrombocytopenia

Leukopenia

Agranulocytosis

Pancytopenia

Psychiatric disorders

Very rare (< 1/10,000):

Hallucinations

Disorientation

Confusion

Anxiety

Agitation

Depression

Impotence

Reduced libido

Nervous system disorders

Common (> 1/100, < 1/10):

Headache

Dizziness

Very rare (< 1/10,000):

Paraesthesia

Somnolence

Insomnia

Epileptic seizures

Gastrointestinal disorders

Common (> 1/100, < 1/10):

Constipation

Diarrhoea

Uncommon (>1/1000, < 1/100):

Nausea

Vomiting

Abdominal discomfort or distension

Flatulence

Fatigue

Dry mouth

Hepato-biliary disorders

Rare (>1/10,000, < 1/1000):

Increase in liver enzyme abnormalities (transaminases, gamma GT, alkaline phosphatase, bilirubin)

Intrahepatic cholestasis (visible sign: jaundice)

Metabolism and nutrition disorders

Uncommon (>1/1000, < 1/100):

Loss of appetite

Skin and subcutaneous tissue disorders

Uncommon (>1/1000, < 1/100):

Rash

Pruritus

Rare (>1/10,000, < 1/1000):

Urticaria

Very rare (< 1/10,000):

Alopecia

Immune system disorders

Rare (>1/10,000, < 1/1000):

Hypersensitivity reactions (angioneurotic oedema, anaphylaxis, bronchospasm)

Respiratory, thoracic and mediastinal disorders

Very rare (< 1/10,000):

Chest tightness

Severe skin reactions (toxic epidermal necrolysis)

Muscoskeletal, connective tissue and bone disorders

Rare (>1/10,000, < 1/1000):

Arthralgia

Very rare (< 1/10,000):

Muscle cramps

4.9 OVERDOSE

No cases of overdose have been reported so far.

Patients suffering from Zollinger-Ellison syndrome have received daily doses of up to 800 mg over a period of one year without exhibiting any significant undesirable effects.

In the event of overdose the aim should be to remove any unabsorbed drug from the alimentary tract.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: A02B A03

Histamine H_2 receptor antagonist.

Famotidine is an effective competitive H_2 receptor antagonist, the effect of which is particularly clearly concentrated on H_2 receptors. It reduces the concentration and amount of acid and pepsin of the gastric juices in the basal and stimulated secretion.

The effect of oral administration of famotidine is rapid. The effect of famotidine is long lasting when recommended doses are used, and it is effective with relatively low concentrations in the blood. The duration of effect, plasma concentration and secretion in the urine are dose dependent.

Oral administration of famotidine leads to the antacid effect starting within an hour of administration. The peak effect is dose dependent and it is achieved within 1-3 hours of administration.

In clinical studies famotidine was found to relieve the pain associated with ulceration, usually during the first week of treatment, and it reduced the gastric acid secretion with one single daily dose at bedtime.

Individual oral doses of 20mg and 40mg effectively inhibited the basal night-time secretion of gastric acid; mean gastric acid secretion was inhibited over a period of 10 hours by 86% and 94%, respectively. The same doses, administered in the morning, inhibited the gastric acid secretion stimulated by eating for 3-5 hours p.a. by a mean of 76% and 84%, respectively. 8-10 hours after administration, the levels were at 25% and 30%, respectively, although the effect of one 20mg dose persisted for only 6-8 hours in some of the volunteers.

The basal night-time intragastric pH value was increased to a mean of 5 and 6.4 by evening doses of 20mg and 40mg of famotidine, respectively. When famotidine was administered after breakfast, the pH value in both the 20mg and the 40mg groups was increased to approximately 5 after 3 and 8 hours.

5.2 PHARMACOKINETIC PROPERTIES

Oral administration.

Absorption. Famotidine is rapidly absorbed. Peak plasma concentration is dose dependent and is achieved within 1-3 hours of administration. The kinetics of famotidine are linear. The bioavailability of oral famotidine is 40-45% on average. Food contained in the stomach will not affect the bioavailability. First pass metabolism of famotidine is minor. Repeat administration will not cause accumulation of the drug in the body.

Distribution in the body. The binding of famotidine in plasma proteins is relatively small (15-20%). The plasma half-life is about 3 hours both after oral single doses and during repeated administration (5 days).

Metabolism. Up to 30-35 % of famotidine is metabolised in the liver to an inactive sulfoxide metabolite.

Excretion from the body. When administered orally, an average of 65-70% of the absorbed famotidine is excreted in the urine. About 25-30% of the total oral dose is excreted unchanged in the urine. The renal clearance of famotidine is 250-450 ml/min, so consequently, excretion also takes place through tubular secretion. A small proportion may be secreted as sulfoxide.

Pharmacokinetics in different patient groups. The average elimination half-life of famotidine in plasma was prolonged to 11.7 hours in patients with creatinine clearance of 30ml/min or less. Patients with maximum creatinine clearance of 10 ml/min had an average plasma half-life of approximately 13 hours. The elimination half-life in these patients may exceed 20 hours. In patients with anuria the elimination half-life was prolonged to about 24 hours. In patients with creatinine clearance of 30 ml/min or less, only 21.2% of the intravenous injection was excreted in the urine.

In men with liver cirrhosis, famotidine plasma concentration and excretion of famotidine in the urine were of the same degree as in healthy trial subjects. Disturbance of liver function apparently has no effect on the pharmacokinetics of famotidine.

Pharmacokinetic studies on elderly patients showed no signs of any clinically significant age-related changes; however, age-related impairment of renal function should be considered when determining the dose.

5.3 PRECLINICAL SAFETY DATA

Preclinical data on famotidine reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Cellulose, microcrystalline. Lactose monohydrate. Macrogol 4000. Magnesium stearate. Hypromellose. Sodium starch glycolate (type A). Silica, colloidal anhydrous . Pregelatanized starch. Talc. Titanium dioxide (E 171).

6.2 INCOMPATIBILITIES

Not applicable

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C

Store in the original package.

6.5 NATURE AND CONTENTS OF CONTAINER

The tablets are packed in Al/PVC blisters which are inserted into a carton folder.

The following sizes of original packages are available:

5, 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets

Not all pack sizes may be marketed

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MARKETING AUTHORISATION HOLDER

Roger Oakes Ltd

Allstoe House

Church Lane,

Greetham,

Rutland, LE15 7NF, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 32019/0033
PL 32019/0034

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/07/2009

10 DATE OF REVISION OF THE TEXT

03/07/2009

PATIENT INFORMATION LEAFLET

Famotidine 20mg and 40mg Film-coated Tablets

Please read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to other people. It may harm them even if their symptoms are the same as yours.
- If any of the side effects become serious or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1 What this medicine is and what it is used for
2 Before you take
3 How to take
4 Possible side effects
5 How to store
6 Further information

1 What this medicine is and what it is used for

Famotidine Tablets belong to a group of medicines called H2-receptor antagonists. These work by work by reducing the amount of acid you produce in your stomach.

Famotidine Tablets are used to treat the following:
- Stomach ulcers (Gastric/Duodenal Ulcers)
- Irritation and inflammation caused by stomach acid leaking up into the gullet (Reflux Oesophagitis)
- Zollinger-Ellison Syndrome (a rare disorder that involves recurrent ulcers and tumours in the stomach and intestines)

2 Before you take

Do not take Famotidine Tablets:
- If you are allergic (hypersensitive) to Famotidine, other H2-receptor antagonists or any of the other ingredients in the tablets (these are listed in Section 6, Further information)
- If you are pregnant, planning to become pregnant or you suspect you are pregnant or if you are breast feeding

Take special care with Famotidine - Tell your doctor if any of the following apply to you:
- If there is a possibility of a growth being present in your stomach
- If there is an underlying infection e.g. Helicobacter Pylori
- If you suffer from kidney problems

Taking other medicines
Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Medicines which **may interact** with Famotidine

- Medicines used to treat fungal infections e.g. Ketoconazole, Itraconazole
- Medicines used to treat gout e.g. Probenicid
- If you are taking antacids for indigestion
- Medicines used to treat and prevent the recurrence of ulcers e.g. Sucralfate

Pregnancy and breast-feeding
If you are pregnant, thinking of becoming pregnant, suspect you are pregnant or breast-feeding, Famotidine Tablets **should not** be taken. Ask your doctor for advice before taking any medicine.

Important information about some of the ingredients of Famotidine
Famotidine contains **lactose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take

Always take Famotidine as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Famotidine tablets should be swallowed whole **(not crushed or chewed)** and with sufficient fluid (e.g. water).

Adults and Elderly

Stomach Ulcers
The recommended dose is 40mg once a day at bedtime. The duration of treatment will normally be between 4-8 weeks. In most cases the ulcer will heal with this treatment within 4 weeks. For treatment of a recurrent ulcer, your doctor may decide it is necessary to take 20mg a day at bedtime.

Zollinger-Ellison Syndrome
The recommended dose is 20mg every six hours. Some patients may require higher doses. Your doctor will decide if this is necessary.

Reflux Oesophagitis
The recommended dose for treating the symptoms of this condition is 20mg twice a day, to be taken for as long as is deemed necessary.
For treatment of an ulcer associated with Reflux Oesophagitis, the recommended dose is 40mg twice a day to be taken for 6-8 weeks.
If long-term treatment of Reflux Oesophagitis is required, the recommended dose is 20mg twice a day. This is not usually recommended beyond 6 months.

Patients with Kidney disorders/on dialysis
If you suffer from kidney disorders, your doctor is likely to reduce your dose. Famotidine tablets should be administered at the end of dialysis or later since some of the active ingredient is removed by dialysis.

Do not change your dose unless your doctor tells you to do so.

Children
Famotidine Tablets are **not** recommended for children.

Continued....

If you taken more Famotidine Tablets than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take FamotidineTablets
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose **do not** take a double dose to make up for a forgotten tablet.

If you stop taking/using Famotidine Tablets
It is important that you keep on taking Famotidine Tablets until the prescribed dose has finished. **Do not** stop taking the tablets even though you may feel better. **Do not stop** or change your treatment before talking to your doctor.

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

4 Possible side effects

Like all medicines, Famotidine Tablets can cause side effects, although not everybody gets them.

Stop taking Famotidine Tablets and seek medical advice immediately if you develop the following symptoms:

- Allergic reactions; swelling of the hands, face, feet, eyelids, lips, tongue, throat
- Difficulty in breathing
- Itching
- Feeling faint
- Fever

Common side effects (affects 1-10 users in 100)
- Headache
- Dizziness (Vertigo)
- Constipation
- Diarrhoea

Uncommon side effects (affects 1-10 users in 1000)
- Feeling or being sick (Nausea/Vomiting)
- Abdominal pain
- Excessive wind/feeling bloated (Flatulence)
- Tiredness (Fatigue)
- Dry mouth (Xerostomia)
- Loss of appetite
- Skin rashes (Exanthema)
- Itching (Pruritus)

Rare side effects (affects 1-10 users in 10,000)
- Yellowing skin and eyes (Jaundice)
- Skin rashes with the formation of wheals (Urticaria)
- Joint pain (Athralgia)

Very rare side effects (affects less than 1 user in 10,000)
- Blood disorders
- Hallucinations
- Disorientation
- Confusion
- Anxiety
- Restlessness (Agitation)
- Depression
- Inability to maintain an erection (Impotence)
- Disorders of sexual function
- Tingling or numbness in the hands or feet (Paraesthesia)
- Sleepiness or drowsiness (Somnolence)
- Difficulty in sleeping (Insomnia)
- Fits (Convulsions)
- Hair Loss (Alopecia)
- Chest tightness
- Severe skin reactions
- Muscle cramps

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Store in the original package. Do not store above 25°C.

Do not use Famotidine Tablets after the expiry date which is stated on the carton/blister after "EXP". The expiry date refers to the last day of that month.

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.

6 Further information

What Famotidine contains:
The active ingredient in each tablet is:
Famotidine 20mg Tablets: 20mg of Famotidine
Famotidine 40mg Tablets: 40mg of Famotidine

Other ingredients are:
Microcrystalline cellulose, lactose monohydrate, macrogol 4000, magnesium stearate, hypromellose, sodium starch glycolate (type A), colloidal anhydrous silica, pregelatinized starch, talc and titanium dioxide (E171).

What Famotidine looks like and contents of the pack:
Famotidine 20 and 40mg: white, oblong, biconvex tablet, scored on one side.

Famotidine is available in:
Famotidine 20 and 40mg Tablets are available in packs of:
5, 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Roger Oakes Ltd
Allstoe House
Church Lane
Greetham
Rutland
LE15 7NF

Manufacturers:
Salutas Pharma GmbH
Otto-Von-Guericke-Allee 1
39179 Barleben
Germany

Product Licence Numbers:
Famotidine 20mg Tablets: PL 32019/0033
Famotidine 40mg Tablets: PL 32019/0034

The leaflet was last revised in November 2008.

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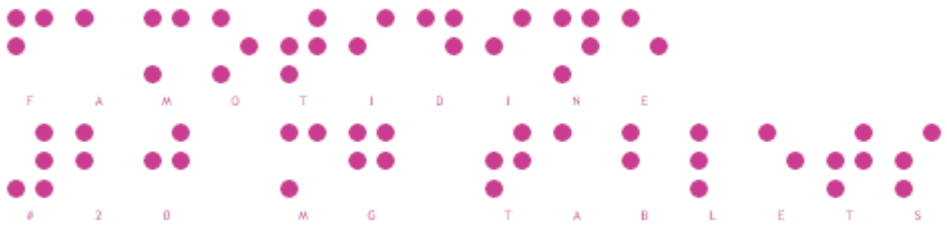
LABELLING

Famotidine 20mg Tablets

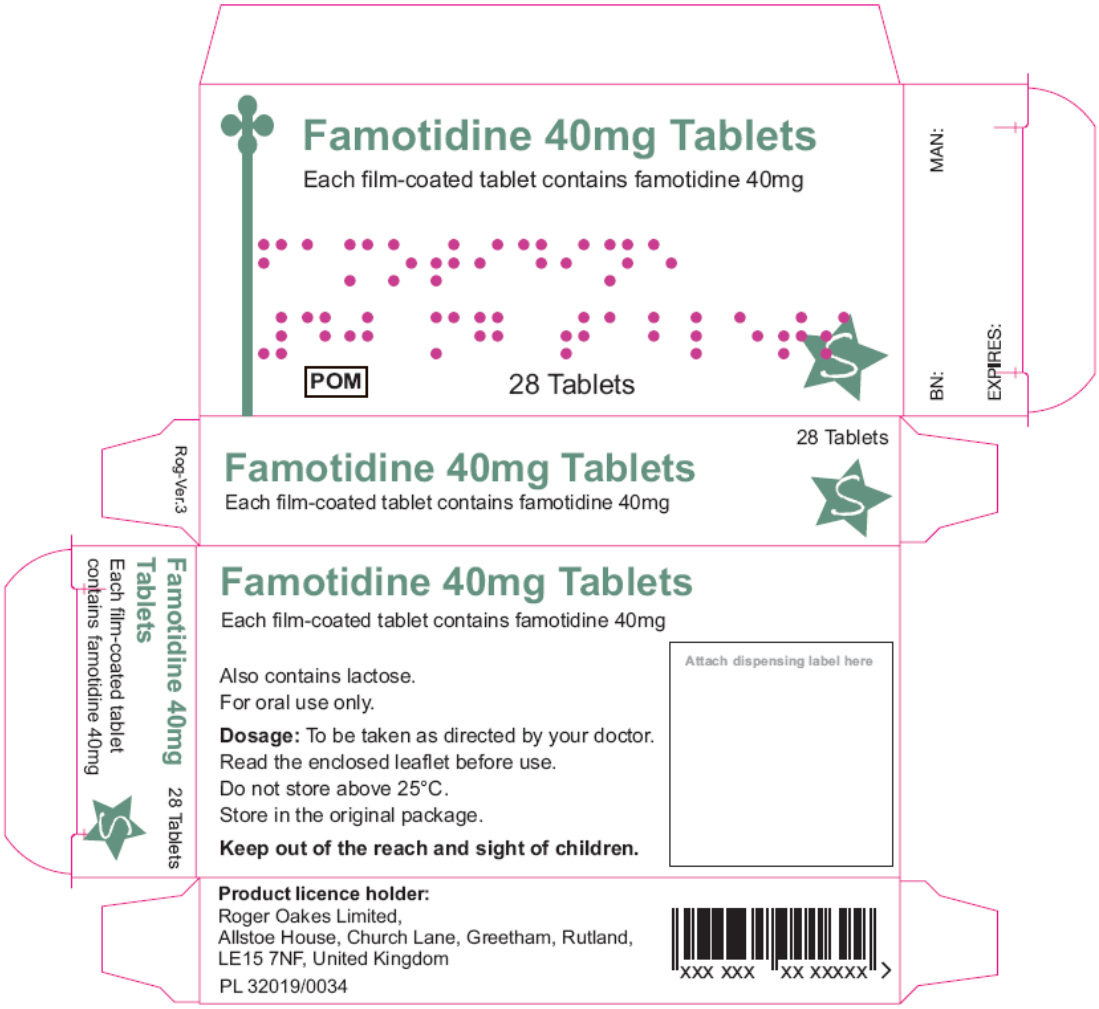
Carton for blisters – pack size 28

Braille



Famotidine 40mg Tablets

Carton for blisters – pack size 28



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