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TECHNICAL DATA SHEET

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## 93186-FAMOTIDINE

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

#### 1.1. Identification of the substance or preparation

Name: Famotidine

Bulk code: 93186

#### 1.2. Synonyms

Propanimidamide, N'-(aminosulfonyl)-3[[[2-[(diaminomethylene)amino]-4-thiazolyl]methyl][thio]3-[[[2-[Aminoiminomethyl]amino]-4-thiazolyl]methyl]tio-N-(aminosulfonyl)oropropanimidamide [1-amino-3-[[[2-[diaminomethylene)amino]-4-thiazolyl]methyl]tio]propylidene]sulfamide 3-[[2-(Diaminomethyleneamino)thiozol-4-yl]methylthio]-N-sulfamoylpropanimidamide N-sulfamoyl-3-[2-guanidinothiazol-4-ylmethylthio]propionamide

### 2. DESCRIPTION

Appearance: Crystalline powder or crystals

Colour: White or yellow-white

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula:  $C_8H_{15}N_7O_2S_3$

CAS: 76824-35-6

Molecular weight: 337.5 g/mol

### 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

**Solubility:** Easily soluble in glacial acetic acid and dimethylformamide, very poorly soluble in water, very poorly soluble in anhydrous ethanol, practically insoluble in ethyl acetate, alcohol, acetone, chloroform and ether. It dissolves in dilute mineral acid.

### 5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT

Famotidine is an imidazolic and cyanoguanidine derivative, an antiulcer agent and gastric acid secretion inhibitor. It is an H<sub>2</sub> histamine antagonist and inhibits H<sub>2</sub> receptor-mediated actions of histamine, such as gastric acid secretion and pepsin production. It is used when inhibition of gastric acid secretion may be beneficial, such as in peptic ulcer disease, including stress ulcers, gastroesophageal reflux disease, selected cases of persistent dyspepsia, pathologic hypersecretory states such as Zollinger-Ellison syndrome, and in patients at risk of acid aspiration during general anaesthesia



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or childbirth.

It can also be used to reduce malabsorption and fluid loss in patients with short bowel syndrome and to reduce the degradation of enzyme supplements given to patients with pancreatic insufficiency.

### 6. DOSAGE

Orally:

- For managing benign gastric and duodenal ulcers, the dose is 40 mg daily taken orally at bedtime, for 4 to 8 weeks. A dose of 220 mg may also be given twice a day. A maintenance dose of 20 mg may be given at bedtime to prevent recurrence of duodenal ulcers.
- In gastro-oesophageal reflux disease, the recommended oral dose is 20 mg twice daily for 6 to 12 weeks, or up to 40 mg twice daily if there is oesophageal erosion or ulcers. A maintenance dose of 20 mg twice daily may be given to prevent recurrence.
- For short-term symptomatic relief of heartburn or non-ulcer dyspepsia, a dose of 10 mg or twice daily is suggested.
- In Zollinger-Ellison syndrome, the initial oral dose is 20 mg every 6 hours, increasing as needed; up to 800 mg daily may be used.

### 7. REMARKS

#### STORAGE:

Store at room temperature ( $25\pm 2^{\circ}\text{C}$ ), in a cool, dry place, away from sunlight, in a tightly closed container.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

### 8. BIBLIOGRAPHY

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011).