# LABELLING STANDARD

## HISTAMINE H2 RECEPTOR ANTAGONIST
## FAMOTIDINE FOR OTC USE

**I) CATEGORY:**

Histamine H2 Receptor Antagonists

**II) DESCRIPTION:**

a) Single ingredient oral dosage forms of the histamine H2 receptor antagonist famotidine at nonprescription strengths for the treatment and prevention of acid-related gastrointestinal symptoms. Maximum daily dosages are limited.

b) **Special Notes:**

i) This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the ***Regulations to the Food and Drugs Act*** and in the **Guide for the Labelling of Drugs for Human Use** should also be met. Famotidine is a new drug and is, therefore, subject to requirements under Division 8 of the *Food and Drug Regulations*.

**III) PHARMACEUTICAL QUALITY:**

a) All ingredient (medicinal and non-medicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the *Food and Drugs Act*, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

i) Pharmacopoeial standards (Schedule B) for formulated preparations are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.

ii) Finished product specifications should include tests for identification, and an assay with suitable limits for the medicinal ingredient(s). The specifications for all dosage forms should include a description of the dosage form, including organoleptic properties, as well as physico-chemical testing, e.g. disintegration/dissolution, weight variation, pH, specific gravity and viscosity appropriate to

the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

**IV) MEDICINAL INGREDIENTS and CONCENTRATIONS:**

Famotidine 10 mg (maximum 20 mg per day)

The medicinal ingredient of a product complying with this standard consists of Famotidine 10 mg when used singly at the strength given.

**V) PERMITTED COMBINATIONS:**

None

**VI) ADEQUATE DIRECTIONS FOR USE:**

**1. Indications**:

i. For the relief of heartburn, indigestion, upset stomach, sour stomach due to excess stomach acid, hyperacidity and/or acid indigestion;

ii. For the prevention of the symptoms of excess stomach acid brought on by consuming food and/or beverages which may cause symptoms;

iii. Controls stomach acid for up to 9 hours.

**2. Claims NOT acceptable**:

i. For night-time relief of symptoms such as heartburn, indigestion, upset stomach, sour stomach due to excess stomach acid, hyperacidity and/or acid indigestion.

ii. For 9-hour relief from symptoms such as heartburn indigestion, upset stomach, sour stomach due to excess stomach acid, hyperacidity and/or acid indigestion.

**3. Dosage Directions**:

Adults and children 12 years of age or over:

i) For the relief of symptoms: One tablet at the onset of symptoms.

ii) For the prevention of symptoms: One tablet one hour before consuming food or beverage which may cause symptoms.

iii) Dose may be repeated if symptoms return, up to a maximum of two doses in a 24-hour period.

**4. Warnings**:

i. If symptoms continue for more than 2 weeks, consult

your doctor.

ii. Consult your doctor or pharmacist before using if:

a) you are taking any prescription or over-the-counter medications such as NSAIDS, sometimes referred to as non-steroidal anti-inflammatory drugs, to treat inflammation, as NSAIDs may be causing your symptoms. (see reference #1 & 2)

b) you are allergic to any ingredient;

c) you are pregnant or breastfeeding;

d) you have difficulty swallowing or persistent abdominal discomfort (stomach pains);

e) you are experiencing unintended weight loss in association with your symptoms of acid indigestion or heartburn;

f) you have severe kidney disease or other severe illness;

g) you are over 40 years of age and you are experiencing new or changed symptoms of acid indigestion or heartburn.

h) you have a previous history of ulcer disease complications

## VII) MISCELLANEOUS LABELLING STATEMENTS

1. Before using Famotidine, **consumer should refer to the Package Insert** (Information for Consumer), containing alternative measures which can help prevent or alleviate symptoms, i.e.:

   i) Avoid foods known to cause symptoms, and avoid or limit foods such as caffeine, chocolate, fatty foods, spicy foods and alcohol

   ii) Do not lie down soon after eating

   iii) If you are overweight, lose weight

   iv) If you smoke, stop or cut down

   v) Do not eat just before bedtime

2. Product monograph available to physicians and pharmacists upon request.

**VIII) REFERENCES:**

1. Essentials of Pharmacology, Cedric M. Smith M.D., Alan M. Reynard, Ph.D., published by W.B. Saunders Company, 1995, page 406-407

2. The People's Guide to Deadly Drug Interactions, Joe Graedon and Teresa Graedon Ph.D., St. Martin's Press, New York

**APPENDIX I**

| **FORMULATED PREPARATIONS** | **U.S.P. XXIII (1995)** | **B.P. (1993)** | **Ph. Eur 3rd ed (1997)** |
|---|---|---|---|
| FAMOTIDINE | X | | X |
| FAMOTIDINE TABLETS | X | | |