

Attachment 2

NOTE:

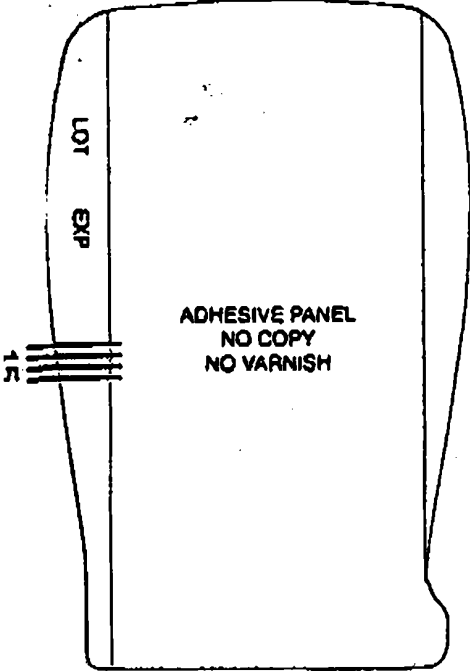
Approval letter contains requests  
for labeling revisions



12 oz Container Label  
front label

5/27/99

20-951



**Clinical Studies**

In clinical studies, Tagamet HB 200 tablets were significantly better than placebo tablets (tablets without the medicine) in relieving and preventing heartburn symptoms. Tagamet HB 200 Suspension contains the same active ingredient.

**Percent of Heartburn Episodes Reduced**

**Study A** **Study B**

Tagamet HB 200 Tablets Placebo 200 Tablets

**Percent of Patients with Prevention or Reduction of Heartburn Symptoms When Taken 30 Minutes Before a Meal**

**Study C** **Study D**

Tagamet HB 200 Tablets Placebo 200 Tablets

**Percent of Patients with Prevention or Reduction of Heartburn Symptoms When Taken at Time of Meal**

**Study E** **Study F**

Tagamet HB 200 Tablets Placebo 200 Tablets



Do not use if printed neck area is missing or torn.

**Drug Facts**

**Active Ingredient (in each 20 mL)** Cimetidine 200 mg

**Purpose** Acid reducer

**Uses**

- for relief of heartburn associated with acid indigestion and sour stomach
- for prevention of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

**Warnings**

**Allergy alert:** do not use if you are allergic to cimetidine or other acid reducers

Do not use

- if you have trouble swallowing
- with other acid reducers

Ask a doctor or pharmacist before use if you are taking

- theophylline (and asthma medicine)
- warfarin (blood thinning medicine)
- phenytoin (seizure medicine)

0766-5015-12

**Drug Facts (continued)**

Brand names of some medicines which contain one of these ingredients include:

**THEOPHYLLINE:** THEO-DUR®  
 Theocron®, Do-Skip®, Uniphy®, Theo-24®  
**WARFARIN:** Coumadin®  
**PHENYTOIN:** Dilantin®

There may be other medicines that contain one of these ingredients. If in doubt about this or about possible effects of Tagamet HB 200 on any other medicines you are taking, ask your doctor or pharmacist.

Stop use and ask a doctor if

- stomach pain continues
- you need to use this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- adults and children 12 years and older: to relieve symptoms, take 4 teaspoons or take 20 mL in pre-measured dose cup provided, with a glass of water
- adults and children 12 years and older: to prevent symptoms, take 4 teaspoons or take 20 mL in pre-measured dose cup provided, with a glass of water right before or every time up to 30 minutes before eating food or drinking beverages that cause heartburn

**Drug Facts (continued)**

- Tagamet HB 200 can be used up to twice daily (4 teaspoon tablet twice in 24 hours)
- children under 12 years of age: Not for use in children under 12 years of age. The safety and efficacy for OTC use in children under 12 years of age has not been proven.

**Other information**

Store between 20°-30° C (68°-86°F)

**Inactive ingredients**

butyrate, FD&C blue #1, flavor, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, saccharin sodium, sucrose, xanthan gum

**Questions or comments?**  
 Call Toll-Free 1-800-423-4234 weekdays

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 Consumer Healthcare LP,  
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**Liquid**

**Tagamet HB 200**

Cimetidine Suspension 200 mg/Acid Reducer

**Heartburn: A discomforting problem**

It is normal for the stomach to produce acid, especially after eating and drinking. Sometimes acid backing up into the esophagus can cause a burning pain and discomfort. This pain and discomfort, commonly known as heartburn, can interfere with everyday activities.

**Tip for Managing Heartburn**

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- if you are overweight, lose weight
- if you smoke, quit smoking
- raise the head of your bed
- wear loose fitting clothing around your stomach

Do not use if printed neck area is missing or torn.

**Drug Facts**

**Active Ingredient (in each 20 mL)** Cimetidine 200 mg

**Purpose** Acid reducer

**Uses**

- for relief of heartburn associated with acid indigestion and sour stomach
- for prevention of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

**Warnings**

**Allergy alert:** do not use if you are allergic to cimetidine or other acid reducers

Do not use

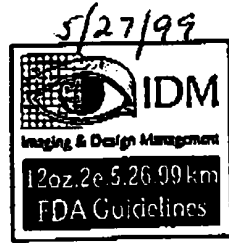
- if you have trouble swallowing
- with other acid reducers

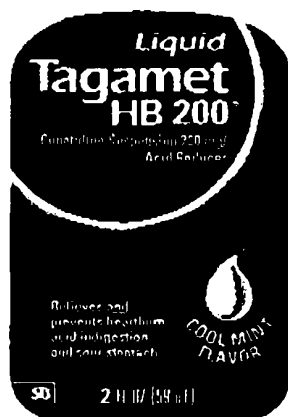
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- warfarin (blood thinning medicine)
- phenytoin (seizure medicine)

0766-5015-12

12 oz container back label

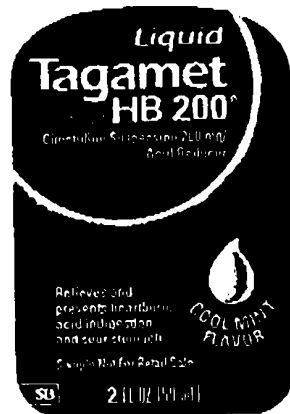




2 Fl. Oz. Trial bottle  
front label

5/27/99





2 FL OZ sample bottle  
front label

5/27/99

Lot & Exp printed on line  
 in this area

4 BAR  
 PHARMACODE  
 1/4" CLEAR ON  
 EACH SIDE OF  
 BAR

**Warnings**

A disconcerting sensation is noted for the stomach to empty and moving. Sometimes the feeling of fullness or bloating can make a burning gas and discomfort. This pain can be relieved by taking an antacid, but should not be used with every day medicine.

**Directions**

- Do not take or heat over heat after eating.
- Do not take at night, or just before bedtime.
- Continue to eat and drink as usual. Do not change location, such as sitting, lying, or standing, during, after, or before taking.
- Do not take with or near food, dairy products, or other foods.
- Do not take with or near alcohol, grapefruit juice, or other grapefruit products.
- Do not take with or near other medicines, especially those for heart, blood pressure, or other conditions.
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**Drug Facts**

Active ingredient (in each 20 mL): **Hydroxyzine Hydrochloride 20 mg**

Other ingredients: **Hydroxyzine Hydrochloride 20 mg**

Use: **For relief of heartburn associated with acid indigestion and gas. It is for prevention of heartburn associated with acid indigestion and gas. It does not relieve heartburn or gas brought on by eating or drinking certain food and beverages.**

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**Drug Facts (continued)**

**Warnings**

Always take: do not use if you are allergic to dimenhydrinate or other anticholinergics

Do not use:

- if you have trouble swallowing
- with other acid reducers
- if a doctor or pharmacist tells you to stop taking it
- if you are taking other medicines, especially those for heart, blood pressure, or other conditions
- if you are taking other medicines, especially those for heart, blood pressure, or other conditions

There may be other medicines that contain one of these ingredients. If in doubt about this or about possible effects of your medicine, ask your doctor or pharmacist.

**Directions**

Take with or without food.

Do not take with or near alcohol, grapefruit juice, or other grapefruit products.

Do not take with or near other medicines, especially those for heart, blood pressure, or other conditions.

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**Drug Facts (continued)**

Always take: do not use if you are allergic to dimenhydrinate or other anticholinergics

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2 Fl. oz. sample  
 back label

