

NOTE:

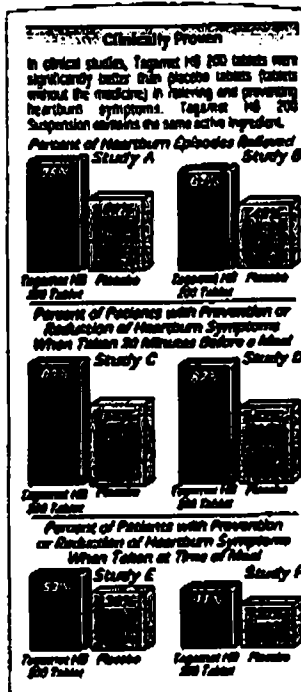
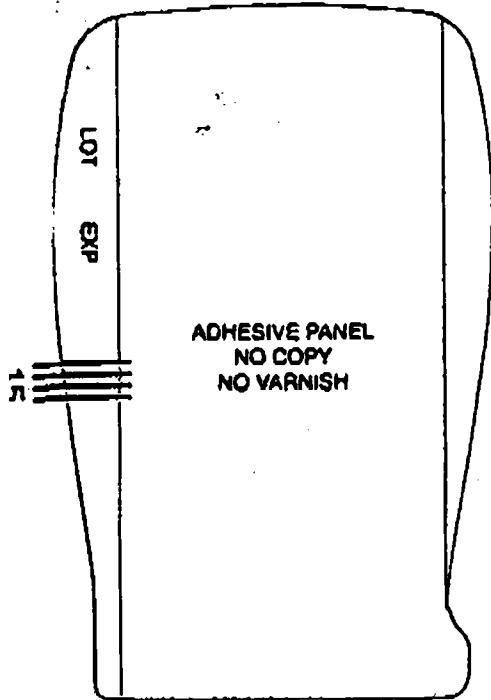
Approval letter contains requests
for labeling revisions



12 oz Container Label
front label

5/27/99

20-951



ADHESIVE PANEL
NO COPY
NO VARNISH

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

Drug Facts

Active Ingredient	Purpose
Cimetidine 200 mg	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 it with other acid reducers

Ask a doctor or pharmacist before use if you are taking

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

3 0766-5015-12 8

Drug Facts (continued)

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

THEOPHYLLINE: THEO-DUR®
Theophrone®, Ste-So®, Uniphy®, Theo-3®
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, talk to 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. Stop use at birth 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 any 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 teaspoons taken 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

hydroxybenzofuran, FD&C Blue #1, flavin, microcrystalline cellulose and croscarmellose sodium, propylene glycol, propylparaben, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

Call Toll-Free 1-800-423-4234 weekdays only.

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Liquid

Tagamet HB 200®

Cimetidine Suspension 20 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.

Typical Warning Signs for 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 check area is missing or torn.

Drug Facts

Active Ingredient	Purpose
Cimetidine 200 mg	Acid reducer

Uses

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Warnings

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

Do not use

- if you have trouble swallowing it with other acid reducers

Ask a doctor or pharmacist before use if you are taking

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

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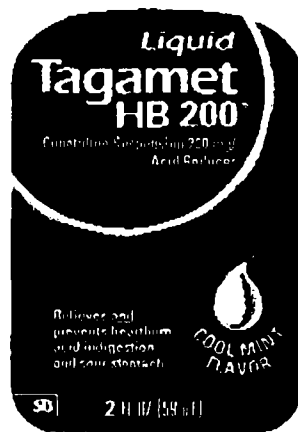
12 oz container back label

5/27/99

Imaging & Design Management

12oz.2e.5.26.99.km

FDA Guidelines



2 Fl. oz. Trial 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

- Do not use for fever or pain over 3 days for adults
- Do not use for more than 10 days for children
- Do not use if you are taking other medications that may increase the risk of bleeding
- Do not use if you are taking other medications that may increase the risk of stomach ulcers
- Do not use if you are taking other medications that may increase the risk of kidney damage
- Do not use if you are taking other medications that may increase the risk of liver damage
- Do not use if you are taking other medications that may increase the risk of heart failure
- Do not use if you are taking other medications that may increase the risk of high blood pressure
- Do not use if you are taking other medications that may increase the risk of diabetes
- Do not use if you are taking other medications that may increase the risk of low blood sugar
- Do not use if you are taking other medications that may increase the risk of dizziness
- Do not use if you are taking other medications that may increase the risk of blurred vision
- Do not use if you are taking other medications that may increase the risk of ringing in the ears
- Do not use if you are taking other medications that may increase the risk of constipation
- Do not use if you are taking other medications that may increase the risk of dry mouth
- Do not use if you are taking other medications that may increase the risk of difficulty swallowing
- Do not use if you are taking other medications that may increase the risk of allergic reactions

In clinical studies, Zepbound 150 tablets were significantly better than placebo tablets (tablets without the medicine)

Cholesterol Lowering

0768-5015-02

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

Drug Facts

Active Ingredients (in each 20 mL): Arginine Aspartate, Acid Reducer

Warnings

- Do not use if you are taking other medications that may increase the risk of bleeding
- Do not use if you are taking other medications that may increase the risk of stomach ulcers
- Do not use if you are taking other medications that may increase the risk of kidney damage
- Do not use if you are taking other medications that may increase the risk of liver damage
- Do not use if you are taking other medications that may increase the risk of heart failure
- Do not use if you are taking other medications that may increase the risk of high blood pressure
- Do not use if you are taking other medications that may increase the risk of diabetes
- Do not use if you are taking other medications that may increase the risk of low blood sugar
- Do not use if you are taking other medications that may increase the risk of dizziness
- Do not use if you are taking other medications that may increase the risk of blurred vision
- Do not use if you are taking other medications that may increase the risk of ringing in the ears
- Do not use if you are taking other medications that may increase the risk of constipation
- Do not use if you are taking other medications that may increase the risk of dry mouth
- Do not use if you are taking other medications that may increase the risk of difficulty swallowing
- Do not use if you are taking other medications that may increase the risk of allergic reactions

Drug Facts (continued)


Active Ingredients: Zepbound 150, Zepbound 200, Zepbound 250, Zepbound 300, Zepbound 350, Zepbound 400, Zepbound 450, Zepbound 500, Zepbound 550, Zepbound 600, Zepbound 650, Zepbound 700, Zepbound 750, Zepbound 800, Zepbound 850, Zepbound 900, Zepbound 950, Zepbound 1000

Warnings

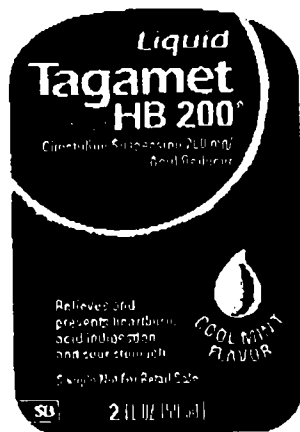
- Do not use if you are taking other medications that may increase the risk of bleeding
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- Do not use if you are taking other medications that may increase the risk of constipation
- Do not use if you are taking other medications that may increase the risk of dry mouth
- Do not use if you are taking other medications that may increase the risk of difficulty swallowing
- Do not use if you are taking other medications that may increase the risk of allergic reactions

2 FL oz. trial size
back label

5/27/99



IMAGING & DESIGN MANAGEMENT
2021.10.5.26.99 km
FDA Guidelines



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
 • Do not use if you are allergic to dimethyl sulfoxide or other acid reducers.
 • Do not use if you have made acid refluxing or with other acid reducers.
 • Do not use if you have a history of peptic ulcer disease or if you are taking other drugs that may interact with this product.
 • Do not use if you are taking other drugs that may interact with this product.
 • Do not use if you are taking other drugs that may interact with this product.

Drug Facts
 Active Ingredient (in each 200 mL)
 Pepsate
 Cimetidine 200 mg
 Uses
 • To relieve heartburn associated with acid indigestion and acid reflux.
 • To relieve heartburn associated with acid indigestion and acid reflux.
 • To relieve heartburn associated with acid indigestion and acid reflux.

Drug Facts (continued)
 Warnings
 • Do not use if you are allergic to dimethyl sulfoxide or other acid reducers.
 • Do not use if you have made acid refluxing or with other acid reducers.
 • Do not use if you have a history of peptic ulcer disease or if you are taking other drugs that may interact with this product.
 • Do not use if you are taking other drugs that may interact with this product.
 • Do not use if you are taking other drugs that may interact with this product.

Drug Facts (continued)
 Contains or contains?
 Contains 200 mg of Pepsate per 200 mL of liquid.
 Contains 200 mg of Pepsate per 200 mL of liquid.
 Contains 200 mg of Pepsate per 200 mL of liquid.

2 Fl. oz. sample
back label

5/27/99



Imaging & Design Management
 2oz 1f.5.26.99km
 FDA Guidelines