GOOD SENSE HEARTBURN RELIEF- cimetidine tablet, film coated L. Perrigo Company

Perrigo Heartburn Relief Drug Facts

Active ingredient (in each tablet)

Cimetidine 200 mg

Purpose

Acid reducer

Uses

- **relieves** heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods 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 or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness**, **sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- kidney disease
- liver disease

Ask a doctor or pharmacist before use if you are taking

• a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- stomach pain continues
- you need to take 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 (1-800-222-1222).

Directions

- adults and children 12 years and over:
- to **relieve** symptoms, swallow 1 tablet with a glass of water
- to **prevent** symptoms, swallow 1 tablet with a glass of water **right before or any time up to 30 minutes before** eating food or drinking beverages that cause heartburn
- do not take more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide

Questions or comments?

1-800-719-9260

Consumer Information

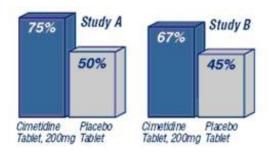
Cimetidine Tablets, 200 mg

Acid Reducer

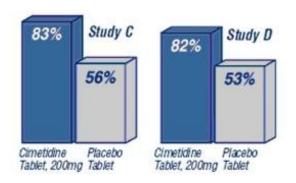
For Heartburn

In clinical studies, Cimetidine Tablets, 200 mg was significantly better than placebo tablets in relieving and preventing heartburn symptoms.

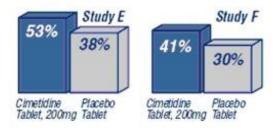
Percent of Heartburn Episodes Relieved



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



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



Drug Interaction Warnings:

Cimetidine Tablets, 200 mg affects some prescription medicines causing slightly higher levels of those medicines in the blood. Higher blood levels could lead to side effects in rare situations. If you currently take Theophylline (oral asthma medicine), Warfarin (blood thinning medicine) or Phenytoin (seizure medicine), consult your doctor before taking this product.

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

| THEOPHYLLINE | THEO-DUR® Theochron® Slo-Bid® Uniphyl® 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 Cimetidine Tablets, 200 mg on any other medicines you are taking, talk to your doctor or pharmacist.

Tips 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

Read the directions and warnings before taking this medication.

Questions or Comments?

1-800-719-9260

Distributed By

Perrigo®

Allegan, MI 49010

Rev 08/19

02200 00 J5

Principal Display Panel

Heartburn Prevention

Heartburn Relief

Actual Size

Cimetidine Tablets, 200 mg

Acid Reducer

JUST ONE TABLET RELIEVES and PREVENTS Heartburn and Acid Indigestion

Take ANYTIME You Need It:

Before Meal

During Meal

After Meal

Compare to active ingredient of Tagamet® HB 200

100% SATISFACTION GUARANTEED

30 Tablets (30 Doses)

Read and retain the important information and drug interaction warnings printed on the product information sheet



GOOD SENSE HEARTBURN RELIEF

cimetidine tablet, film coated

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0113-0022 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CIMETIDINE (UNII: 80061L1WGD) (CIMETIDINE - UNII:80061L1WGD) | CIMETIDINE | 200 mg | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | |
| PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E) | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | |

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

| Product Characteristics | | | |
|-------------------------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 13mm |
| Flavor | | Imprint Code | L022 |
| Contains | | | |

| | Packaging | | | | | |
|---|--------------------|---|-----------------------------|--------------------|--|--|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| ı | 1 NDC:0113-0022-39 | 1 in 1 CARTON | 12/30/2002 | | | |
| ı | 1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA075285 | 12/30/2002 | | |
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Labeler - L. Perrigo Company (006013346)

Revised: 2/2020 L. Perrigo Company