

RANITIDINE- ranitidine hydrochloride tablet, film coated
Health Mart

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Ranitidine 75 mg (as ranitidine hydrochloride USP, 84 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 ranitidine 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

Stop use and ask a doctor if

- your heartburn continues or worsens
- 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 **30 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- children under 12 years: ask a doctor

OTHER INFORMATION

- **TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.**
- store at 20° - 25° C (68° - 77° F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

INACTIVE INGREDIENTS

Colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, talc, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

NDC 62011-0225-2

HealthMart®

PHARMACY

compare to Zantac 75® active ingredient†

ranitidine tablets, USP 75 mg

acid reducer

prevents and relieves heartburn associated with acid indigestion and sour stomach

regular strength

60 tablets

Distributed by McKesson

5104343/0713



RANITIDINE

ranitidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:62011-0225
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (RANITIDINE)	RANITIDINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
COLLOIDAL SILICON DIOXIDE	
CROSCARMELOSE SODIUM	

HYPROMELLOSES	
FERRIC OXIDE RED	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL 400	
TALC	
TITANIUM DIOXIDE	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	OR;606
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0225-2	1 in 1 CARTON		
1		60 in 1 BOTTLE		
2	NDC:62011-0225-1	1 in 1 CARTON		
2		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201745	09/20/2013	

Labeler - Health Mart (177667227)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Limited		915786829	manufacture(62011-0225)

Revised: 8/2013

Health Mart