# ACID REDUCER- ranitidine tablet, film coated Good Sense

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**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

- vour 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 INDIVIDUAL BLISTER UNIT 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

**GOODSENSE**<sub>®</sub>

NDC 50804-352-31

**Regular Strength** 

Ranitidine Tablets, USP 75 mg

**Acid Reducer** 

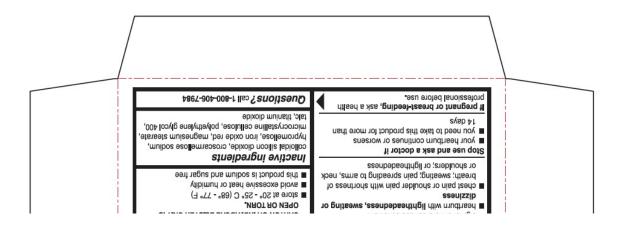
Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach

30 Tablets

Compare to active ingredient of Zantac 75<sup>®†</sup>

Distributed by: Geiss, Destin and Dunn, Inc

5105600/1013





#### ACID REDUCER

ranitidine tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-352	
Route of Administration	ORAL			

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7) RANITIDINE 75 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:50804-352-08	1 in 1 CARTON			
1	80 in 1 BOTTLE			
2 NDC:50804-352-31	3 in 1 CARTON			
2	10 in 1 BLISTER PACK			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA201745	10/11/2013		

### Labeler - Good Sense (076059836)

## Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shasun Pharmaceuticals Limited		915786829	manufacture(50804-352)	

Revised: 10/2013 Good Sense