

**RANITIDINE- ranitidine tablet, film coated**  
**Fred's Inc.**

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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**

- 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**

**freds<sup>®</sup>**

**Ranitidine Tablets, USP 75 mg**

**Acid Reducer**

**Regular Strength**

**Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach**

**30 Tablets**

†Compare to Active Ingredient of Zantac 75<sup>®</sup>

**DISTRIBUTED BY: fred's, Inc.**

**5102619/0513**



## RANITIDINE

ranitidine tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-352
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### 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:55315-352-31	1 in 1 CARTON		
1		30 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201745	09/01/2013	

**Labeler** - Fred's Inc. (005866116)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

### Establishment

Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Inc.		915786829	manufacture(55315-352)

Revised: 7/2013

Fred's Inc.