ACID REDUCER- ranitidine tablet Fred's Inc.

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 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 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
- if you have kidney disease, except under the advice and supervision of a doctor

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, talc, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

fred's®

Maximum Strength

Ranitidine Tablets, USP

150 mg

Acid Reducer

Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach

50 TABLETS

[†]Compare To the active ingredient of Zantac 150®

DISTRIBUTED BY: fred's, Inc.

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Drug Facts (continued)

ACID REDUCER

ranitidine tablet

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55315-351

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7)	RANITIDINE	150 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2 IP)		

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	9 R
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55315-351-50	1 in 1 CARTON		
1	50 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200536	03/30/2012	

Labeler - Fred's Inc. (005866116)

Establishment			
Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Limited		915786829	manufacture(55315-351)

Revised: 1/2013 Fred's Inc.