RUGBY CALCIUM CARBONATE 10 GR- antacid tablets tablet, chewable Aphena Pharma Solutions - Tennessee, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Calcium carbonate 10 gr (648 mg)

Purpose

Antacid

Uses

Relieves:

- acid indigestion
- heartburn
- sour stomach
- acid indigestion
- upset stomach associated with these symptoms

Warnings

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor is symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Directions

- take one to four tablets daily
- do not take more than 4 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks

Other Information

each tablet contains: calcium 260mg

store at room temperature 15^{0} - 30^{0} C (59^{0} - 86^{0} F)

Inactive ingredients

corn starch, crospovidone, magnesium stearate, maltodextrin

Questions or comments

Repackaging Information

This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	648mg
30	43353-958-30
60	43353-958-53
90	43353-958-60
100	43353-958-65
180	43353-958-80
200	43353-958-85
270	43353-958-92

Store between 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

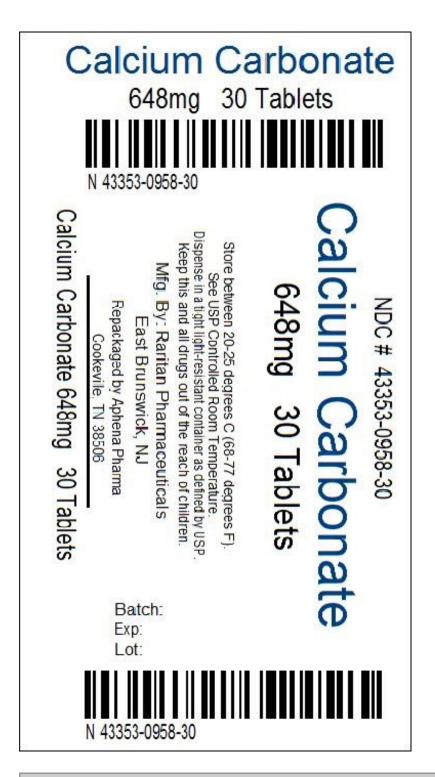


Cookeville, TN 38506

20160606DH

PRINCIPAL DISPLAY PANEL - 648mg

NDC 43353-958 - Calcium Carbonate 648mg - Rx Only



RUGBY CALCIUM CARBONATE 10 GR

antacid tablets tablet, chewable

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:43353-958(NDC:0536	-1024)	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength	Strength	

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	RP106
Contains			

Packaging **Marketing Start Marketing End** # Item Code **Package Description** Date Date NDC:43353-958-30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 1 09/02/2014 30 Product NDC:43353-958-60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 2 08/01/2014 53 Product 3 NDC:43353-958-90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 08/01/2014 60 Product 4 NDC:43353-958-100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 07/26/2014 65 Product 5 NDC:43353-958-180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination $0\,8/0\,1\!/20\,1\!4$ 80 Product 200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination NDC:43353-958-6 07/29/2014 85 Product 7 NDC:43353-958-270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 08/01/2014 92 Product **Marketing Information**

Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpart33102/07/201402/07/2014				
OTC monograph final part331 02/07/2014	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph final	part331	02/07/2014	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(43353-958)