RUGBY EXTRA STRENGTH ANTACID - calcium carbonate tablet, chewable Rugby Laboratories

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.

Rugby Extra Strength Antacid Assorted Fruit Chewable Tablets

ACTIVE INGREDIENT (in each tablet)

Calcium carbonate 750 mg

PURPOSE

Antacid

USE(S)

relieves:

- acid indigestion
- heartburn

WARNINGS

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

• presently taking a prescription drug. Antacids may interact with certain prescription drugs.

WHEN USING THIS PRODUCT

do not take more than 10 tablets in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

IF PREGNANT OR/BREASTFEEDING,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS

• adults and children 12 years of age and over: chew 2-4 tablets as symptoms occur, or as directed by a doctor.

OTHER INFORMATION

- each tablet contains: elemental calcium 300 mg
- do not use if printed seal under cap is torn or missing.
- store at room temperature. Keep the container tightly closed.

INACTIVE INGREDIENTS

adipic acid, corn starch, crospovidone, D&C red 27 lake, D&C red 30 lake, D&C yellow 10 lake, dextrose, FD&C blue 1 lake, FD&C yellow 6 lake, flavors, magnesium stearate, maltodextrin, sucrose, talc.

PRINCIPAL DISPLAY PANEL

COMPARE TO the active ingredient of TUMS® EXTRA STRENGTH* NDC 0536-1225-22 Rugby CALCIUM Antacid Tablets Extra Strength Calcium Carbonate 750 mg Assorted Fruit Naturally & Artificially Flavored 96 Chewable Tablets



RUGBY EXTRA STRENGTH ANTACID

calcium carbonate tablet, chewable

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sourc	e)	NDC:0536	-1225
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ing		Basi: Stren		Strength	

Inactive Ingredients

Ingredient Name	Strength
ADIPIC ACID (UNII: 76A0JE0FKJ)	
STARCH, CORN (UNII: 08232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ 35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics						
Color	ORANGE, YELLOW, GREEN, PINK (reddish pink)	Score	no score			
Shape	ROUND	Size	16mm			
Flavor	CHERRY, LEMON, LIME, ORANGE	Imprint Code	G127			
Contains						

Packaging

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#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1225- 22	96 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part331	03/14/2019	

Labeler - Rugby Laboratories (079246066)

Establishment					
Name	Address	ID/FEI	Business Operations		
Guardian Drug Company		119210276	MANUFACTURE(0536-1225)		