TOPCARE ULTRA STRENGTH ANTACID ASSORTED BERRY - calcium carbonate tablet, chewable Topco Associates, 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.

TopCare Ultra Strength Antacid Assorted Berry

ACTIVE INGREDIENT (in each tablet)

Calcium carbonate 1000 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 7 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

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DIRECTIONS

• adults and children 12 years of age and over: chew 2-3 tablets as symptoms occur, or as directed by a doctor.

OTHER INFORMATION

- each tablet contains: elemental calcium 400 mg
- do not use if printed seal under the cap is torn or missing
- store at room temperature. keep the container tightly closed.

INACTIVE INGREDIENTS

adipic acid, corn starch, crospovidone, dextrose, FD&C blue 1 lake, FD&C red 40 lake, flavors, magnesium stearate, maltodextrin, sucrose, talc.

PRINCIPAL DISPLAY PANEL

TopCare_® health

NDC 76162-130-68 COMPARE TO TUMS® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Antacid Tablets

CALCIUM CARBONATE 1000 mg

RELIEVES:

- Upset Stomach
- Heartburn
- Acid Indigestion

ASSORTED BERRY FLAVORS
72 CHEWABLE TABLETS





TOPCARE ULTRA STRENGTH ANTACID ASSORTED BERRY

calcium carbonate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-130
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII: 2M83C4R6ZB)	CALCIUM CARBONATE	1000 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ADIPIC ACID (UNII: 76A0JE0FKJ)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSPOVIDONE (UNII: 2S7830E561)		
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ 35W2)		
FD&C BLUE NO. 1ALUMINUM LAKE (UNII: J9EQA3S2JM)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
SUCROSE (UNII: C151H8M554)		
TALC (UNII: 7SEV7J4R1U)		

FD&C RED NO. 40 (UNII: WZB9127XOA)

Product Characteristics			
Color	BLUE, PINK	Score	no score
Shape	ROUND	Size	17mm
Flavor	RASPBERRY, STRAWBERRY	Imprint Code	G171
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:76162-130- 68	72 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	04/26/2022	

Labeler - Topco Associates, LLC (006935977)

Revised: 4/2022 Topco Associates, LLC