

SUNMARK EXTRA STRENGTH ANTACID ASSORTED FRUIT - calcium carbonate tablet, chewable

Strategic Sourcing Services 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.

Sunmark 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

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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

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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

sunmark

COMPARE TO TUMS® E-X ACTIVE INGREDIENT*

NDC 70677-0065-1

antacid tablets

Extra Strength

Calcium Carbonate 750 mg

Fast Relief of heartburn & acid indigestion

ASSORTED FRUIT

96 CHEWABLE TABLETS



SUNMARK EXTRA STRENGTH ANTACID ASSORTED FRUIT

calcium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0065
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB,	CALCIUM	750 mg

CARBONATE ION - UNII:7UJQ5OPE7D)		CARBONATE	750 mg	
Inactive Ingredients				
Ingredient Name		Strength		
ADIPIC ACID (UNII: 76A0JE0FKJ)				
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0065-1	96 in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part331	09/18/2019		

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70677-0065)