GOODSENSE EXTRA STRENGTH ANTACID - calcium carbonate tablet, chewable GoodSense

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.

GoodSense Extra Strength Antacid Assorted Berry 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 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

GOODSENSE Extra Strength NDC 50804-129-22

Antacid

Tablets
Calcium Carbonate 750 mg
Antacid

Fast Relief of:

- Heartburn
- Acid Indigestion
- Upset stomach

Assorted Berry Flavors Compare to active ingredient of Extra Strength Tums®* 96 CHEWABLE TABLETS





GOODSENSE EXTRA STRENGTH ANTACID

calcium carbonate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-129
Route of Administration	ORAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
ADIPIC ACID (UNII: 76A0JE0FKJ)		

STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SUCROSE (UNII: C151H8 M554)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	BLUE, PINK, PINK (PINKISH BLUE)	Score	no score
Shape	ROUND	Size	16 mm
Flavor	BERRY (STRAWBERRY, RASPBERRY, WIDBERRY)	Imprint Code	G127
Contains			

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:50804-129-22	96 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	08/30/2018	

Labeler - GoodSense (076059836)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(50804-129)	

Revised: 11/2018 GoodSense