HEB EXTRA STRENGTH ANTACID - calcium carbonate tablet, chewable H E B

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.

HEB Extra Strength Antacid Assorted Fruit Chewable Tablets

ACTIVE INGREDIENT (in each tablet)

Calcium carbonate 750 mg

PURPOSE

Antacid

USE(S)

relieves:

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

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 carton is open or individual foil wrapping is damaged.
- store at room temperature.

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 Tums® Extra Strength active ingredient*
NDC 37808-135-12
H E B
Extra Strength
Antacid Tablets
Calcium Carbonate, 750 mg
Antacid
Relief of:

- Acid Indigestion
- Heartburn

Assorted Fruit Flavors

24 CHEWABLE TABLETS 3 ROLLS / 8 TABLETS EACH



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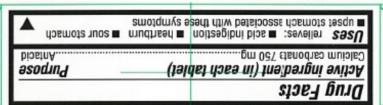
If pregnant or breast-feeding, ask a health professional before use.

under the advice ard supervision of a doctor.

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Orug Facts (continued)



Compare to Tums® Extra Strength active ingredient*

NDC 37808-135-12



Extra Strength

Antacid Tablets

Calcium Carbonate, 750 mg



Relief of: • Acid Indigestion • Heartburn

Assorted Fruit Flavors

24 CHEWABLE TABLETS 3 ROLLS / 8 TABLETS EACH

INNER UNITS NOT LABELED FOR INDIVIDUAL RETAIL SALES.

*This product is not manufactured or distributed by GlaxoSmithKline. TUMS® is a Registered trademark of GlaxoSmithKline.



8585 1807 MFR# 53041 REV 1217



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calcium carbonate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-135
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK) (CALCIUM CATION - UNII: 2M8 3C4R6 ZB)	CALCIUM CARBONATE	750 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ADIPIC ACID (UNII: 76 A0 JE0 FKJ)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSPO VIDO NE, UNSPECIFIED (UNII: 2S7830 E561)		
DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTO DEXTRIN (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	16 mm
Flavor	CHERRY, LEMON, LIME, ORANGE	Imprint Code	G127
Contains			

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:37808-135-12	3 in 1 CARTON	10/24/2018		
ı	1	8 in 1 PACKAGE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	10/24/2018	

Labeler - HEB (007924756)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(37808-135)	

Revised: 10/2018 HE B