EXTRA STRENGTH SMOOTH ANTACID - calcium carbonate tablet, chewable Thirty Madison Inc

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.

Extra Strength Smooth Antacid Chill Berries

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 BREAST FEEDING,

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.
- do not take for symptoms that persists for more than 2 weeks unless advised by a doctor.

OTHER INFORMATION

- each tablet contains: elemental calcium 300 mg
- store at room temperature. keep the container tightly closed.

INACTIVE INGREDIENTS

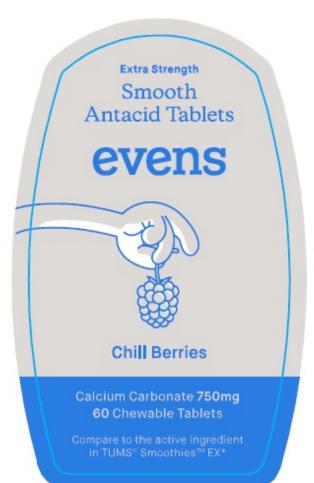
adipic acid, corn starch, dextrose, FD&C blue 1 lake, FD&C red 40 lake, flavors, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose, talc.

PRINCIPAL DISPLAY PANEL

Extra Strength Smooth Antacid Tablets evens Chill Berries Calcium Carbonate 750 mg

60 Chewable Tablets

Compare to the active ingredient in TUMS® SmoothiesTM EX



Drug Facts

Active ingredient Purpose (in each tablet)

Calcium carbonate 750 mg____.Antacid

Uses relieves: ■ acid indigestion ■ heartburn sour stomach upset stomach associated with these symptoms

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.

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING.



CLEAR

AREA (DO NOT ALTER SIZE)

EXP:

Drug Facts (continued)

CONTINUING DRUG FACTS

If pregnant or breast-feeding, 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. do not take for symptoms that persist for more than 2 weeks unless advised by a doctor.

Other information

each tablet contains: elemental calcium 300 mg store at room temperature. Keep the container tightly closed.

Inactive ingredients adipic acid, corn starch, dextrose, FD&C blue 1 lake, FD&C red 40 lake, flavors, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose, talc.

*This product is not manufactured or distributed by GlaxoSmithKline, the distributor of TUMS® Smoothies™ EX.

Distributed by Thirty Madison, Inc. New York, NY 10016

STOP PEELING HERE

EXTRA STRENGTH SMOOTH ANTACID

calcium carbonate tablet, chewable

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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)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
SORBITOL (UNII: 506T60A25R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	RED (light red), BLUE (light blue), PINK (light pink)	Score	no score
Shape	ROUND	Size	16mm
Flavor	BERRY (STRAWBERRY, RASPBERRY, WIDBERRY), CHERRY	Imprint Code	G173
Contains			

# Item Code Package Description Date Date	Packaging			
	# Item Code	Package Description		Marketing End Date
1 NDC:71713-204- 60 in 1 BOTTLE; Type 0: Not a Combination Product 05/17/2019			05/17/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	05/17/2019	

Labeler - Thirty Madison Inc (080774087)

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