

ALKA-SELTZER ULTRA STRENGTH HEARTBURN RELIEFCHEWS- calcium carbonate tablet, chewable
Bayer HealthCare 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.

Alka-Seltzer Ultra Strength Heartburn ReliefChews UI

Drug Facts

Active ingredient (in each chewable tablet)

Calcium carbonate 1000 mg

Purpose

Antacid

Uses

Uses for the relief of:

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

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients

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 5 chewable tablets in a 24-hour period
- do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician
- constipation may occur

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

Keep out of reach of children

Directions

Directions

- adults and children 12 years and over: fully chew then swallow 1 or 2 chewable tablets as symptoms occur, or as directed by a doctor
- children under 12 years: consult a doctor

- do not take more than 5 chewable tablets in a 24-hour period

Other

Other information

- **each chewable tablet contains:** calcium 400 mg
- store at room temperature. Avoid humidity.
- close cap tightly after use

Inactive ingredients acacia, annatto extract, ascorbyl palmitate, beta carotene, carnauba wax, citric acid, confectioners sugar, corn syrup, disodium EDTA, dl-alpha-Tocopherol, FD&C Red #40 aluminum lake, FD&C Yellow #6 aluminum lake, flavors, hydrogenated coconut oil, lecithin, maltodextrin, methylparaben, modified starch, potassium hydroxide, potassium sorbate, propylene glycol, propylparaben, shellac, silicon dioxide, sodium ascorbate, sorbic acid, sorbitol, sugar, titanium dioxide, turmeric oleoresin, vegetable oil, water, white wax

Questions or comments?

1-800-986-0369 (Mon – Fri 9AM – 5PM EST)

Package label 50 count

tropical twist

Alka-Seltzer®

Calcium Carbonate/Antacid

ULTRA STRENGTH

HEARTBURN

RELIEFCHEWS®

FAST POWERFUL RELIEF

50 CHEWABLE TABLETS

Do not use if printed safety seal bearing "SEALED for YOUR PROTECTION" under cap is torn or missing. Bayer, the Bayer Cross, Alka-Seltzer and ReliefChews are registered trademarks of Bayer. Made in the USA of US & Imported Materials. Dist. by: Bayer HealthCare LLC Whippany, NJ 07981. C6408 Bayer

Drug Facts (continued)	Directions ● adults and children 12 years and over: fully chew then swallow 1 or 2 chewable tablets as symptoms occur, or as directed by a doctor ● children under 12 years: consult a doctor ● do not take more than 5 chewable tablets in a 24-hour period	Other information ● each chewable tablet contains: calcium 400 mg ● store at room temperature. Avoid humidity ● close cap tightly after use	Inactive ingredients acacia, annatto extract, ascorbyl palmitate, beta carotene, carnauba wax, citric acid, confectone's sugar, corn syrup, disodium EDTA, dl-alpha-Tocopherol, FD&C Red #40 aluminum lake, FD&C Yellow #6 aluminum lake, flavors, hydrogenated coconut oil, lecithin, maltodextrin, methylparaben, modified starch, potassium hydroxide, potassium sorbate, propylene glycol, propylparaben, shellac, silicon dioxide, sodium ascorbate, sorbic acid, sorbitol, sugar, titanium dioxide, turmeric oleoresin, vegetable oil, water, white wax.
Drug Facts	Active ingredient (in each chewable tablet) Calcium carbonate 1000 mg.....Antacid	Uses (for the relief of): ● acid indigestion ● heartburn ● sour stomach ● upset stomach associated with these symptoms	Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients 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 5 chewable tablets in a 24-hour period ● do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician ● constipation may occur If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children.
Questions or comments? 1-800-368-0888 (Mon-Fri 9AM-5PM EST)			

ALKA-SELTZER ULTRA STRENGTH HEARTBURN RELIEFCHEWS

calcium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0245
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
SHELLAC (UNII: 46N107B710)	
POTASSIUM SORBATE (UNII: 1VPU26JZ4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TURMERIC (UNII: 856YO1Z64F)	
ANNATTO (UNII: 6PQP1V1B6O)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM ASCORBATE (UNII: S033EH8359)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
STARCH, POTATO (UNII: 8I089SAH3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CORN OIL (UNII: 8470G57WFM)	
PALM OIL (UNII: 5QUO05548Z)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
ACACIA (UNII: 5C5403N26O)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
WHITE WAX (UNII: 7G1J5DA97F)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
CORN SYRUP (UNII: 9G5L16BK6N)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	yellow, orange	Score	no score
Shape	ROUND	Size	18mm
Flavor	MANGO, PEACH, TROPICAL FRUIT PUNCH	Imprint Code	U2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0245-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	03/01/2017	

Labeler - Bayer HealthCare LLC. (112117283)