

**LEADER EXTRA STRENGTH ANTACID - calcium carbonate tablet, chewable
CARDINAL HEALTH 110, LLC. DBA LEADER**

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.

Leader 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

Leader™

NDC 70000-0430-2

Extra Strength Antacid Tablets

Calcium Carbonate, 750 mg

Assorted Fruit Flavor

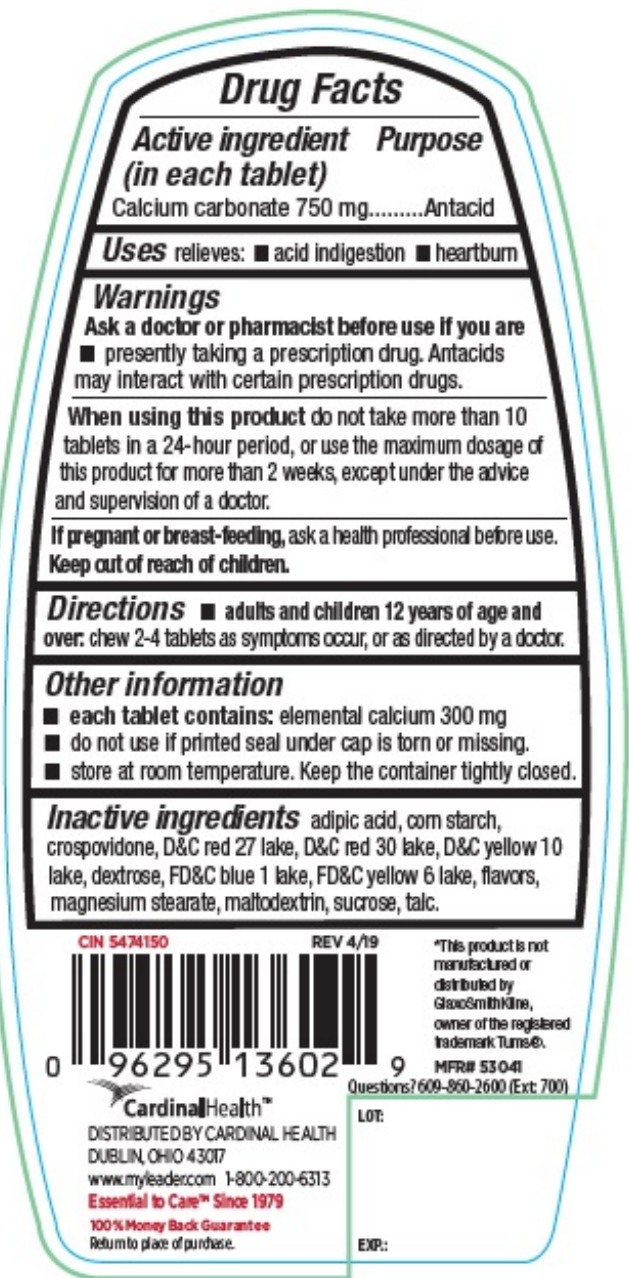
Relief of :

Heartburn and

Acid Indigestion

COMPARE TO TUMS® EXTRA STRENGTH active ingredient*

96 CHEWABLE TABLETS



LEADER EXTRA STRENGTH ANTACID

calcium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0430
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
ADIPIIC ACID (UNII: 76A0JE0FKJ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (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:70000-0430-2	96 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	07/10/2019	

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70000-0430)