EXTRA STRENGTH HEARTBURN RELIEF- aluminum hydroxide and magnesium carbonate suspension
CARDINAL HEALTH

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.

LDR ES heartburn relief

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 254 mg
Magnesium carbonate 237.5 mg

Purpose

Antacid

Uses

relieves

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

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- laxative effect may occur
- do not use maximum dosage for more than 2 weeks
- do not take more than 16 teaspoonfuls in 24 hours

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- shake well before use
- adults and children 12 years and older take 2-4 teaspoonsful four times a day or as directed by a doctor
- children under 12 years: consult a doctor
- take after meals and at bedtime

- dispense product only by spoon or other measuring device

Other information

- **each 5 mL teaspoonful contains:** magnesium 70 mg, sodium 16 mg
- store at room temperature
- protect from freezing
- keep tightly closed
- **TAMPER-EVIDENT**: Do not use this product if inner foil seal over mouth of the bottle is broken or missing.

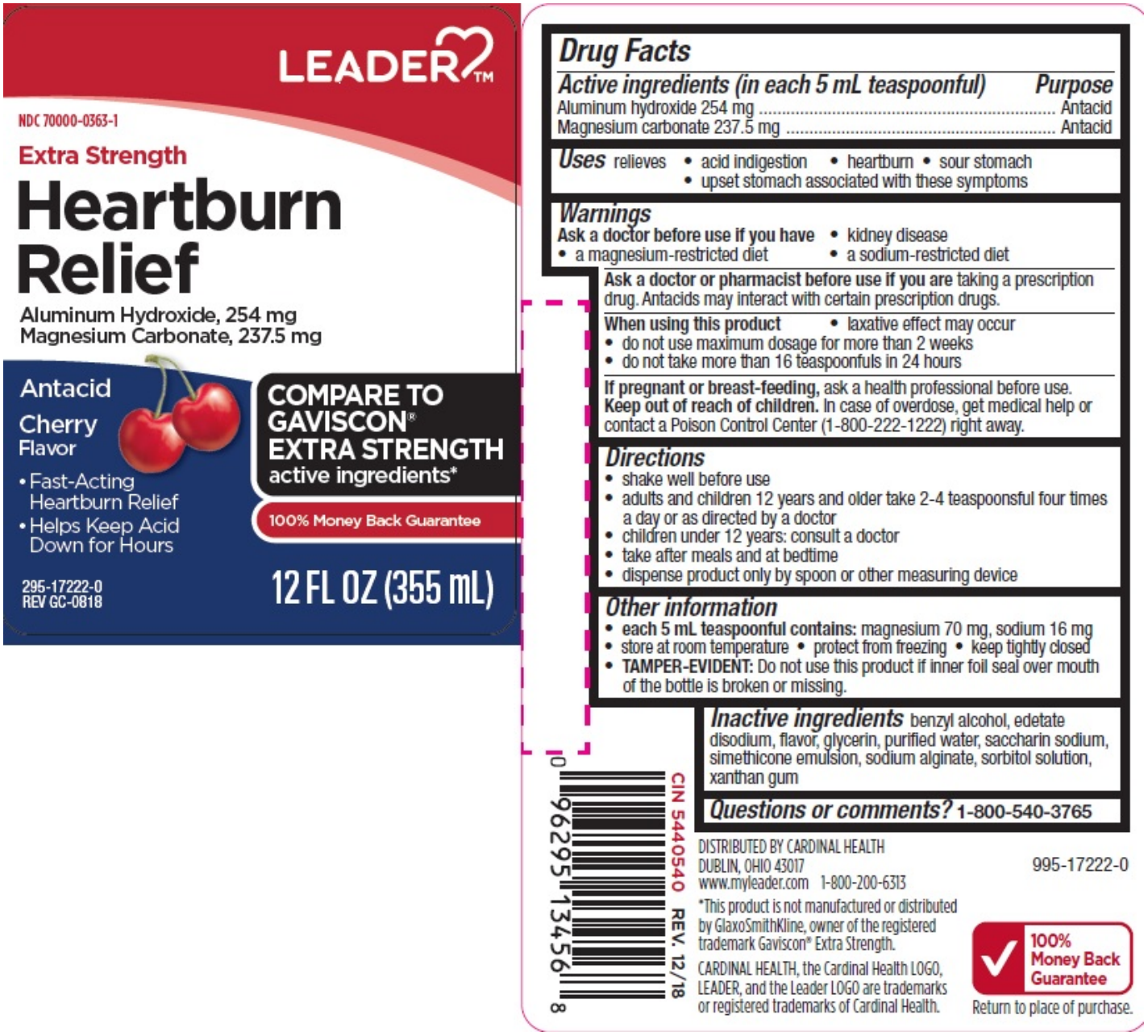
Inactive ingredients

benzyl alcohol, edetate disodium, flavor, glycerin, purified water, saccharin sodium, simethicone emulsion, sodium alginate, sorbitol solution, xanthan gum

Questions or comments?

1-800-540-3765

package Label



EXTRA STRENGTH HEARTBURN RELIEF

aluminum hydroxide and magnesium carbonate suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0363
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	254 mg in 5 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	237.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0363-1	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/01/2019	

Labeler - CARDINAL HEALTH (097537435)

Registrant - GCP Laboratories (965480861)

Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(70000-0363)

Revised: 11/2019 CARDINAL HEALTH