

LEADER GAS RELIEF- simethicone 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 Gas Relief Chewable Tablets

ACTIVE INGREDIENT(in each tablet)

Simethicone 80 mg

PURPOSE

Antigas

USE(S)

relieves:

- pressure
- bloating
- symptoms referred to as gas

WARNINGS

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KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by a physician

OTHER INFORMATION

- do not use if inner seal is broken
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

INACTIVE INGREDIENTS

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.

PRINCIPAL DISPLAY PANEL

NDC 70000-0434-1

LEADER™
Gas Relief

Simethicone, 80 mg
Antigas
Mint Flavor

For Relief of :
Pressure, Bloating, Symptoms Referred to as Gas

100 CHEWABLE TABLETS

LEADER™
NDC 70000-0434-1

Gas Relief

Simethicone, 80 mg | Antigas

Mint Flavor
For Relief of:
Pressure, Bloating,
Symptoms Referred
to as Gas

100 CHEWABLE TABLETS

100% Money Back Guarantee

Drug Facts

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Directions ■ chew 2 to 4 tablets thoroughly as needed after meals and at bedtime ■ do not exceed 6 tablets per day unless directed by a physician

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
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✓ All LEADER™ Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

MFR# 53041
CIN 5474192
REV 3/19
LOT: 9629513606
EXP: 7
Questions? 1-800-860-2600 (Ext. 700)

LEADER GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0434
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	80 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SUGARCANE (UNII: 81H2R5AOH3)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SORBITOL (UNII: 506T60A25R)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	PEPPERMINT	Imprint Code	G103	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0434-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/07/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332		06/07/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70000-0434)

Revised: 1/2022

CARDINAL HEALTH 110, LLC. DBA LEADER