

**GAS RELIEF- simethicone tablet, chewable**  
**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.*

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**Leader 44-137-Delisted**

***Active ingredient (in each tablet)***

Simethicone 80 mg

***Purpose***

Antigas

***Uses***

- relieves these symptoms associated with gas:
  - bloating
  - pressure
  - fullness
  - stuffed feeling

***Warnings***

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

***Directions***

- chew 1 to 2 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- use by expiration date on package

***Inactive ingredients***

dextrose, peppermint flavor, silica gel, sorbitol, stearic acid, talc, tri-calcium phosphate

**Principal Display Panel**

**NDC 37205-112-78**

**LEADER®**

**Gas Relief**

Simethicone 80 mg

**Anti Gas**

• Pressure • Bloating • Discomfort

**Fast Acting**

**SATISFACTION GUARANTEED**

Mint Flavored

**100 CHEWABLE TABLETS**

50844 REV0712G13712

**Questions or comments? 1-800-426-9391**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

CIN 2804144

All **Leader**<sup>®</sup> Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**



Leader 44-137

**GAS RELIEF**

simethicone tablet, chewable

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-112
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
PEPPERMINT (UNII: V95R5KMY2B)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DEXTROSE (UNII: IY9XDZ35W2)	

## Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	44;137
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-112-78	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/28/1994	02/04/2023

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	07/28/1994	02/04/2023

**Labeler** - CARDINAL HEALTH(097537435)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(37205-112)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(37205-112)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(37205-112)

## Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 3/2020

CARDINAL HEALTH