

GAS RELIEF - simethicone tablet, chewable
Physicians Total Care, Inc.

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 44-137

Active ingredients

Simethicone 80 mg

Purpose

Antigas

Use(s)

relieves these symptoms associated with gas

- bloating
- pressure
- stuffed feeling
- fullness

Warnings

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

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

Other information

- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

Inactive ingredients

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

Principal display panel

NDC 54868-2860-0



Simethicone 80 mg

Gas Relief

•Pressure •Bloating •Discomfort

Fast Acting

Anti Gas

Mint Flavored

100 Tablets

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

50844 REV1104E13712

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

Additional barcode labeling by:

Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

GAS RELIEF			
simethicone tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2860(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	
DEXTROSE (UNII: IY9XDZ35W2)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
TALC (UNII: 7SEV7J4RIU)			

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:54868-2860-0	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	05/17/1995	

Labeler - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 5/2012

Physicians Total Care, Inc.