GAS RELIEF- simethicone capsule, liquid filled Publix Super Markets 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.

Publix Super Markets, Inc. Gas Relief Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Anti-gas

Use

relieves bloating, pressure or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists

Keep out of reach of children.

Directions

- swallow one or two softgels as needed after a meal
- do not exceed two softgels per day except under the advice and supervision of a physician

Other information

- each softgel contains: potassium 5 mg
- store at 68°-77°F (20°-25°C)

Inactive ingredients

FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin

Principal Display Panel

Р

ULTRA STRENGTH

gas relief

ANTI-GAS/SIMETHICONE 180 mg

Relief of:

- Pressure
- Bloating
- Gas Discomfort

EASY TO SWALLOW

Compare to the active ingredient of Phazyme[®] Ultra Strength 60 SOFTGELS (180 mg)



GAS RELIEF

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-657
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	180 mg
Inactive Ingredients		

Strength

Ingredient Name

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	ORANGE	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	L657
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-657- 72	1 in 1 CARTON	11/18/2003	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	11/18/2003	

Labeler - Publix Super Markets Inc (006922009)

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