GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled SMART SENSE (Kmart)

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.

Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Uses

• for the relief of pressure, bloating, and fullness commonly referred to as gas

Warnings

If pregnant of breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours unless directed by a doctor

Other information

- store at controlled room temperature 20-25°C (68-77°F)
- protect from light, heat, and moisture

Inactive ingredients

D&C yellow #10, edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, medium-chain triglycerides*, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

*may contain this ingredient

Questions or comments?

Call toll free 1-800-842-7886

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN GAS-X® SOFTGELS†

gas relief

EXTRA STRENGTH

SIMETHICONE 125 mg / ANTIGAS

FAST RELIEF OF:

pressure • bloating • discomfort

small • easy to swallow

SOFTGELS

 $\dagger This$ product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Gas-X® Softgels.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

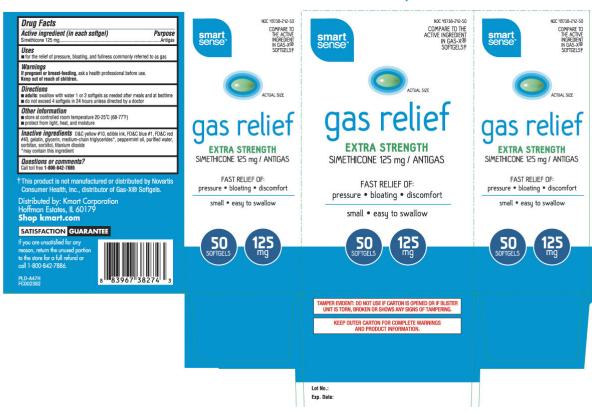
Distributed by: Kmart Corporation

Hoffman Estates, IL 60179

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Product Label





Gas Relief ExtraStrength Softgels

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-242
Route of Administration	ORAL		

ı	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICO NE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients	
Ingredient Name	Strength

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	9 mm	
Flavor		Imprint Code	PO;S1;SCU	
Contains				

	Packaging				
l	# Item Co	de	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:49738-	242-50 50 in 1	CARTON	12/31/2014	12/31/2021
	1	1 in 1 B	LISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	12/31/2014	12/31/2021

Labeler - SMART SENSE (Kmart) (008965873)

Revised: 12/2018 SMART SENSE (Kmart)