GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled Family Dollar (FAMILY WELLNESS)

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 between 20-25°C (68-77°F)
- do not refrigerate
- protect from light, heat, and moisture

Inactive ingredients

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

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN GAS-X® EXTRA STRENGTH*

Gas Relief

SIMETHICONE 125 mg ANTIGAS

FAST RELIEF OF

PRESSURE - BLOATING - DISCOMFORT

EXTRA STRENGTH

SOFTGELS

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X® Extra Strength.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Product Label



FAMILY WELLNESS Extra Strength Gas Relief

GAS RELIEF EXTRA STRENGTH						
simethicone capsule, liquid filled						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:55319-487		
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Sti	rength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)			DIMETHICONE		125 mg	
Inactive Ingredients						

	Ing	redient Name	Strength
D&C YELLOW NO.	10 (UNII: 355W5US	Q3G)	
FD&C BLUE NO. 1	(UNII: H3R47K3TBD)		
FD&C RED NO. 40	(UNII: WZB9127XOA)	
GELATIN (UNII: 2G8	36QN327L)		
GLYCERIN (UNII: PE	DC6A3C0OX)		
PEPPERMINT OIL ((UNII: AV092KU4JH)		
WATER (UNII: 059Q	F0KO0R)		
SORBITAN (UNII: 60	O92ICV9RU)		
SORBITOL (UNII: 50	06T60A25R)		
TITANIUM DIOXIDI	e (UNII: 15FIX9V2JP)		
MANNITOL (UNII: 3	OWL53L36A)		
Product Chara	acteristics		
Color	green	Score	no score
Chana	OVAL	Size	9mm
Snape			DO-C CU-1125
Shape Flavor		Imprint Code	PO;SCU;L125

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55319-487- 50	50 in 1 CARTON	02/29/2016	10/30/2025		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:55319-487- 30	30 in 1 CARTON	02/29/2016	10/30/2025		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
Marketing Information						
	Marketing	Application Number or Monograph	Marketing Start	Marketing End		

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part347	02/29/2016	10/30/2025

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023

Family Dollar (FAMILY WELLNESS)