

EXTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled
Shopko Stores Operating Co., LLC.

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

Antiflatulent

Uses

for relief of:

- bloating
- pressure
- fullness
- stuffed feeling commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists.

If pregnant or breast- feeding

ask a health care professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **adults:** swallow with water 1 or 2 softgels as needed after meals or at bedtime. Do not exceed 4 softgels per day, unless directed by a doctor.

Other information

- store at controlled room temperature 15°- 30° C (59°- 86° F)
- protect from heat and moisture
- *This product is not manufactured or distributed by Novartis Consumer Healthcare Inc., owner of the registered trademark Extra Strength Gas-X®.

Inactive ingredients

D&C yellow #10, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil and titanium dioxide. May also contain: purified water and sorbitol special.

principal display panel

Extra Strength Gas Relief

ANTIGAS

SIMETHICONE 125 mg

Relieves:

- **bloating**
- **pressure**
- **fullness**
- **gas**

*Compare to **Extra Strength Gas-X® active ingredient**

Packaged by: PL Developments

200 hicks street

westbury, NY 11590 USA

QUESTIONS OR COMMENTS?

call toll free 1-877-753-3935

**EACH TABLET IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF
BLISTER UNIT IS TORN OR BROKEN.**

Product Label



SIMETHICONE 125 MG

EXTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-550
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-550-30	2 in 1 CARTON		
1		15 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	06/02/2010	

Labeler - Shopko Stores Operating Co., LLC. (023252638)