

**EXTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled
Greenbrier International, 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.

Extra Strength Gas Relief Simethicone, 125 mg Anti-Gas 15 Softgels

Active ingredient (per each softgel)

Simethicone 125 mg

Purpose

Antigas

Use

for the relief of

- Pressure, bloating, and fullness commonly referred to as gas

Warnings

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 except under the advice and supervision of a physician.

Other information

- store at room temperature
- protect from light, heat, and moisture

Inactive ingredients

D&C yellow 10, FD&C blue 1, FD&C red 40, gelatin, glycerin, peppermint oil, purified water, titanium dioxide

Questions or comments

1-866-467-2748

Principal Display Panel



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

Assured

Extra Strength

Gas Relief

SIMETHICONE, 125mg

ANTI-GAS

Relieves:

- Bloating
- Pressure
- Fullness
- Gas

15 SOFTGELS

*This product is not manufactured or distributed by GSK Consumer Healthcare, Inc., the distributor of Gas-X® Extra strength.

Distributed by:
 Greenbrier International, Inc.
 Chesapeake, VA 23320

IMPORTANT: Keep this carton for future reference on full labeling.

DO NOT USE IF ANY INDIVIDUAL BLISTER IS BROKEN OR OPEN

EXTRA STRENGTH GAS RELIEF				
simethicone capsule, liquid filled				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-3113	
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)				
WATER (UNII: 059QF0KO0R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	GREEN (Opaque)	Score	no score	
Shape	OVAL	Size	10mm	
Flavor		Imprint Code	PC2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-3113-5	1 in 1 CARTON	01/19/2018	
1		15 in 1 BLISTER 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	part332	01/19/2018	

Labeler - Greenbrier International, Inc. (610322518)

Revised: 12/2017

Greenbrier International, Inc.