

**ASSURED GAS RELIEF EXTRA STRENGTH EXTRA STRENGTH- 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.

Assured Gas Relief 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

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
- do not use if any individual blister unit is broken or missing

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, FD&C blue 1, gelatin, glycerin, purified water, titanium dioxide

Principal Display Panel

Compare to active ingredient in Extra Strength Gas-X®

Extra Strength

Gas Relief

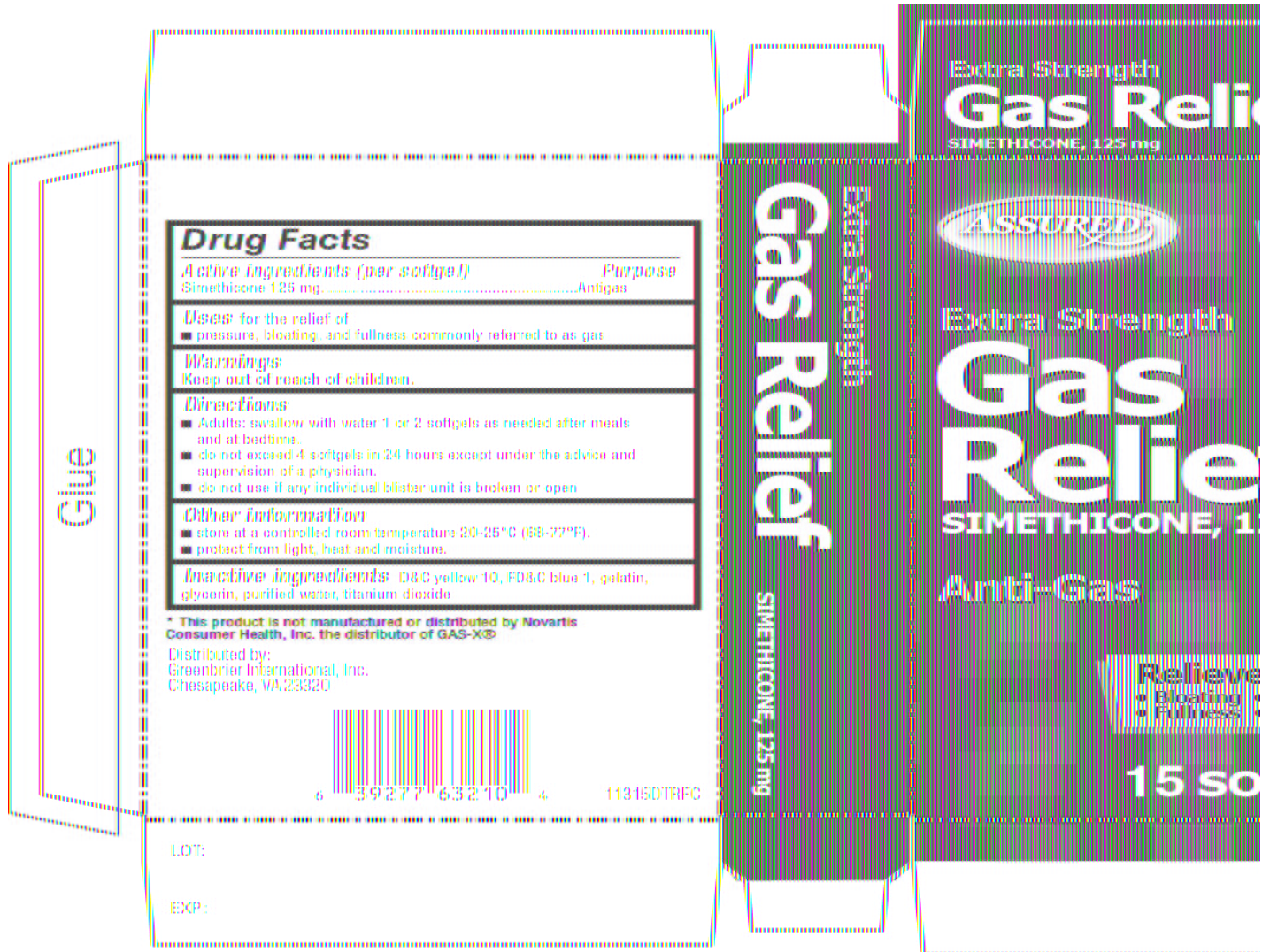
Simethicone 125 mg

Anti-Gas

Relieves:

Bloating, Pressure, Fullness, Gas

15 Softgels



Assured Gas Relief Extra Strength

ASSURED GAS RELIEF EXTRA STRENGTH EXTRA STRENGTH			
simethicone capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0113
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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	10 mm
Flavor		Imprint Code	R113
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0113-1	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	01/06/2012	

Labeler - Greenbrier International, Inc. (610322518)

Revised: 1/2013

Greenbrier International, Inc.