EXTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled Geri-Care Pharmaceuticals, Corp

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.

gc792l (692)

Active ingredient (in each liquid-filled capsule)

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 capsules as needed after meals and at bedtime
- do not exceed 4 capsules in 24 hours unless directed by a doctor

Other information

- **Tamper Evident**: Do not use if imprinted seal under cap is missing or broken.
- Product of China, Packaged and Quality Assured in the USA.
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from light, heat and moisture

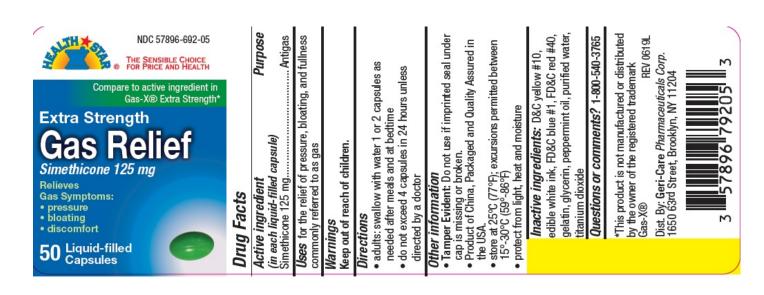
Inactive ingredients

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

Questions or comments?

1-800-540-3765

package label



EXTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-692
Route of Administration	ORAL		

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

Inactive Ingredients			
Ingredient Name	Strength		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
WATER (UNII: 059QF0KO0R)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
GELATIN (UNII: 2G86QN327L)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

Product Characteristics					
Color	green	Score	no score		
Shape	OVAL	Size	9 mm		
Flavor		Imprint Code	664		
Contains					

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:57896-692-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part332	06/01/2019			

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 12/2019 Geri-Care Pharmaceuticals, Corp