

SIMETHICONE- simethicone capsule, liquid filled
SPIRIT PHARMACEUTICALS LLC

Extra Strength Gas Relief

Active ingredient (in each softgel)

Simethicone 125mg

Purpose

Antigas

Use

for the relief of

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

Warning

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 controlled room temperature 20-25°C (68-77°F)
- protect from light, heat, and moisture

Inactive ingredients

FD&C blue 1, FD&C yello#10, gelatin, glycerin, peppermint oil, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Extra Strength

Gas Relief
Simethicone 125 mg - Antigas

- relieves gas fast • pressure • bloating • discomfort

15 Softgels



SIMETHICONE

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4129
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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4129-1	1 in 1 CARTON	04/27/2021	
1		15 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	04/27/2021	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)