

SIMETHICONE- simethicone capsule, liquid filled
SPIRIT PHARMACEUTICALS 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.

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

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

Extra Strength Gas Relief

SIMETHICONE 125 MG / ANTIGAS

RELIEVES GAS FAST

PRESSURE

BLOATING

DISCOMFORT

†This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Extra Strength Gas-X®



SIMETHICONE

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-3130
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)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

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:68210-3130-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/16/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 3/2020

SPIRIT PHARMACEUTICALS LLC