

SIMETHICONE- simethicone capsule, gelatin coated
Spirit Pharmaceuticals LLC

ULTRA STRENGTH GAS RELIEF

Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Antigas

Use

for the relief of

■ pressure and bloating commonly referred to as gas

Warnings

Keep out of reach of children.

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 2 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 heat and moisture

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, peppermint oil, povidone, purified water, sorbitol solution, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

ULTRA STRANGTH

GAS RELIEF

Simethicone 180 mg /
anti-gas

Fast relief of:

- bloating
- pressure
- fullness
- gas

50 SOFTGELS



SIMETHICONE

simethicone capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0314
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (OPAQUE)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	161
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0314-5	1 in 1 CARTON	03/10/2020	
1		50 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	03/10/2020	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(68210-0314)

Revised: 12/2023

Spirit Pharmaceuticals LLC