

SIMETHICONE 125MG GAS RELIEF- simethicone 125 mg capsule, liquid filled
One2Zee Limited Liability Company

Simethicone 125mg Gas Relief

Drug Facts

Active Ingredients (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Use for the relief of

- pressure
- bloating
- 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
- do not use if imprinted safety seal under cap is broken or missing

D&C yellow 10, FD&C blue 1, FD&C red 40, gelatin, glycerin, povidone, peppermint oil, purified water, sorbitol, titanium dioxide

Questions or comments?

Call 1-833-663-2933



NDC 55629-021-01

**EXTRA STRENGTH
GAS RELIEF**

Simethicone 125 mg
anti-gas

Relieves

- Gas Pain
- Pressure
- Bloating

365 Softgels

Compare to the active ingredient in
Extra Strength Gas-X*

Drug Facts
Active Ingredients (in each softgel) Purpose Simethicone 125 mg Antigas
Uses for the relief of ■ pressure ■ bloating ■ 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.
Other Information ■ store at room temperature 20° – 25°C (68° – 77°F) ■ protect from light, heat and moisture ■ do not use if imprinted safety seal under cap is broken or missing
Inactive Ingredients D&C yellow 10, FD&C blue 1, FD&C red 40, gelatin, glycerin, povidone, peppermint oil, purified water, sorbitol, titanium dioxide
Questions or comments? Call 1-833-883-2833

MP/DRUGS/25/4/2011

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



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Distributed by:
OneZee LLC
Edison, NJ 08837

Lot No.

Exp. Date

SIMETHICONE 125MG GAS RELIEF

simethicone 125 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55629-021
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: 355W5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	Z25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-021-01	365 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	09/11/2024	

Labeler - One2Zee Limited Liability Company (078656111)

Revised: 9/2024

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