GAS RELIEF- simethicone capsule, liquid filled Advanced Rx LLC

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

If pregnant or breast-feeding, ask a health professional before use.

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 20° to 25°C (68° to 77°F)
- protect from light, heat and moisture
- DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

D&C Yellow 10, FD&C Blue 1, Edible Ink, Gelatin, Glycerin, Peppermint oil, POLYSORB, Purified water, Titanium dioxide.

Questions?

call **1-800-630-8895**

Distributed by:

Advanced Rx LLC

1942 NE 163rd St North Miami Beach,

FL 33162 U.S.A.

NDC 80513-117-12

Extra Strength

GAS RELIEF

Simethicone 125 mg

DIC 80513-117-12 EXTRA STRENGTH GAS RELIEVES Simethicone 125 mg • RELIEVES GAS FAST • PRESSURE • BLOATING • DISCOMFORT	DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED Druid Facts		USE for the relief of pressure, bloating, and fullness, commonly referred to as gas.	Warnings If pregnant or breast-feeding, ask a health professional before use, 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	● <i>Other information</i> ■store at 20° to 25°C (68° to 77°F) ■ protect from light, heat and moisture	<i>Inactive ingredients</i> D&C Yellow 10, FD&C Blue 1, Edible Ink, Gelatin, Glycerin, Peppermint oil, POLYSORB, Purified water, Titanium dioxide.	Questions? ca l 1-800-630-8895	Distributed by: Advanced Rx 1942 NE 163rd St North Miami Beach, FL 33162 U.S.A.	
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GAS RELIEF

simethicone capsule, liquid filled

Product Information								
Product Type	HUMAN OTC I	DRUG	NDC:80513-117					
Route of Administration	ORAL							
Active Ingredient/Active	e Moiety							
Ingr	Basis of St	trength	Strength					
DIMETHICONE (UNII: 92RU3N3Y1	.0) (DIMETHICON	NE - UNII:92RU	J3N3Y1O)	DIMETHICONE		125 mg		
Inactive Ingredients								
Ingredient Name						Strength		
D&C YELLOW NO. 10 (UNII: 35S	W5USQ3G)							
FD&C BLUE NO. 1 (UNII: H3R47K	(3TBD)							
GELATIN (UNII: 2G86QN327L)								
GLYCERIN (UNII: PDC6A3C0OX)								
PEPPERMINT OIL (UNII: AV092KU4JH)								
WATER (UNII: 059QF0K00R)								
TITANIUM DIOXIDE (UNII: 15FIX9	V2JP)							
Product Characteristics	;							
Color gr	reen	Score		r	no score			
Shape O'	VAL	Size		1	L0mm			
Flavor		Imprint Co	de	Q	911			

Contains							
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:80513-117	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025					
Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Dr	ug M002	01/01/2025					
OTC Monograph Dr	ug M002	01/01/2025					

Labeler - Advanced Rx LLC (042795108)

Establishment						
Name	Address	ID/FEI	Business Operations			
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(80513-117)			

Revised: 1/2025

Advanced Rx LLC