

**GAS RELIEF- simethicone capsule, liquid filled
THIRTY MADISON INC**

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.

Thirty Madison Inc Gas Relief Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Use

for the relief of

- pressure, bloating and 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 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Gas-X® Active Ingredient

evens

Gas Relief

Anti-Gas Simethicone 125 mg

Relieves discomfort, pressure, and bloating

Actual size

Extra strength

30 softgels



GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71713-401
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L428
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71713-401-01	30 in 1 CARTON	01/04/2022	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/04/2022	

Labeler - THIRTY MADISON INC (080774087)