

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled
Fred's 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.

Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Uses

- for the relief of pressure, bloating, or 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 unless directed by a doctor

Other information

- store at controlled room temperature 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, medium-chain triglycerides*, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

*may contain this ingredient

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Extra Strength Gas Relief

Simethicone 125 mg

Antigas

Relief of:

Bloating

Pressure

Fullness

Gas

*Compare to active ingredient in: **Gas-X®*****

Softgels

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

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD., MEMPHIS, TN 38118

www.fredsinc.com

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Product Label



NDC 55315-242-30

Extra Strength



Actual Size

Gas Relief

Simethicone 125 mg Antigas

Relief of:
Bloating
Pressure
Fullness
Gas



Compare to the active ingredient in:
GAS-X***

30 Softgels

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Lot No.:
 Exp. Date:

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fred's Promise
 Not Happy With This Product?
 Just Bring It Back For a Refund!



PLD-D
 FC001622

Fred's Extra Strength Gas Relief Softgels

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-242
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO;S1;SCU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-242-30	1 in 1 CARTON	10/30/2013	12/31/2020
1		15 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	part347	10/30/2013	12/31/2020

Labeler - Freds Inc (005866116)

Revised: 12/2018

Freds Inc