GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled QUALITY CHOICE (Chain Drug Marketing Association)

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, and fullness commonly referred to as gas

Warnings

If pregnant of 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 between 15-30°C (59-86°F)
- do not refrigerate
- 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, sorbitan, sorbitol, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in GAS-X® Extra strength⁺

Gas Relief

Extra Strength

Simethicone 125 mg/Antigas

For Relief of:

Bloating

Pressure

Fullness

Gas

Softgels

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X® Extra Strength.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by C.D.M.A., Inc. $\ensuremath{\mathbb{C}}$

43157 W. 9 Mile Rd

Novi, MI 48376-0995

www.qualitychoice.com

Product Label



QUALITY CHOICE Gas Relief Extra Strength
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GAS RELIEF EXTRA STRENGTH									
simethicone capsule, liquid filled									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:63868-236					
Route of Administration	ORAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of S	Strength	Strength				
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)			DIMETHICON	Έ	125 mg				
Inactive Ingredients									

		Strength						
D&C YELLOW NO. 10								
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)								
FD&C RED NO.40 (UN								
GELATIN (UNII: 2G86Q								
GLYCERIN (UNII: PDC6								
PEPPERMINT OIL (UN								
WATER (UNII: 059QF0F								
SORBITAN (UNII: 6092								
SORBITOL (UNII: 506T60A25R)								
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)								
Product Characteristics								
Color	GREEN	Score	no score					
Shape	OVAL	Size	9 mm					
Flavor		Imprint Code	PO;SCU;L12	25				
Contains								
Packaging								
# Item Code	Package I	Description	Marketing Start Date	Marketing End Date				
1 NDC:63868-236-30	30 in 1 CARTON	n 1 CARTON						
1	1 in 1 BLISTER PACK; Type	0: Not a Combination Product						
Marketing Information								
Marketing Categor	y Application Numbe	r or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC MONOGRAPH FINA			03/31/2016	-				

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2019

QUALITY CHOICE (Chain Drug Marketing Association)