# 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.

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#### **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 or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

In case of overdose get medical help or contact a Poison Control Center (1-800-222-1222) right away

#### **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 physican

#### Other information

- store between 20-25°C (68-77°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, mannitol,

peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

#### **Questions or comments?**

Call **1-800-935-2362** 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.©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

#### **Product Label**



**QUALITY CHOICE Extra Strength Gas Relief** 

Lot No.: Exp. Date:

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# **GAS RELIEF EXTRA STRENGTH**

simethicone capsule, liquid filled

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63868-300

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 30WL53L36A)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868-300- 30	30 in 1 CARTON	09/30/2019	09/30/2025	
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	part347	09/30/2019	09/30/2025

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

Revised: 5/2023 QUALITY CHOICE (Chain Drug Marketing Association)