

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled
Kareway Product, 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 Ingredients (in each softgel)

Simethicone 125mg

Purpose

Antiflatulent

Uses

For Relief of:

- Bloating
- Pressure
- Fullness
- stuffed feeling commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **adults:** swallow with water 1 or 2 softgels as needed after meals or at bedtime. Do not exceed 4 softgels per day, unless directed by doctor.

Other information

- store at a controlled room temperature 15-30°C (59-86°F)
- protect from heat and moisture

Inactive ingredients

FD&C blue 1, FD&C yellow 5, gelatin, glycerin, purified water, titanium dioxide

Package/Label Principal Display Panel



GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0172
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	GR
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0172-1	10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	09/01/2012	

Labeler - Kareway Product, Inc. (121840057)

Revised: 10/2012

Kareway Product, Inc.