

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled
BJWC (Berkley & Jensen / BJ's)**

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

Antiflatulent (Antigas)

Use

- relieves bloating, pressure, or fullness 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 and at bedtime.
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician.

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- protect from 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 special and titanium dioxide.

Questions or comments?

call toll free: **1-800-934-1204 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in Extra Strength Gas-X®*

Extra Strength

Gas Relief

Simethicone, 125 mg

Relieves:

- bloating
- fullness
- pressure
- gas

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

DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Simethicone 125 mg

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6839 1-550
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)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-550-12	8 in 1 CARTON		
1		15 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	07/15/2013	

Labeler - BJWC (Berkley & Jensen / BJ's) (159082692)

Registrant - P and L Development of New York Corporation (800014821)

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BJWC (Berkley & Jensen / BJ's)