GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled McKesson (Sunmark)

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

Principal Display Panel

Compare to Extra Strength Gas-X® active ingredient*

Gas Relief

Extra Strength

- Discomfort
- Pressure
- Bloating

Simethicone 125 mg

Relieves gas symptoms

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

Another quality product distributed by McKesson

one post street, San Francisco, CA 94104

Money back gurantee

Please visit us at www.sunmarkbrand.com

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

Product Label





Simethicone 125 mg

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-946	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICO NE (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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
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
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49348-946-44	2 in 1 BOX			
1		15 in 1 BLISTER PACK			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part347	04/12/2011		

Labeler - McKesson (Sunmark) (177667227)

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