

MAJOR EXTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled

Major Pharmaceuticals

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)

Uses

- 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 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?

1-800-616-2471

Principal Display Panel

MAJOR®

Gas Free

Extra Strength Gas Relief

ANTIGAS

SIMETHICONE 125 mg

Relieves:

- **bloating**
- **pressure**
- **fullness**
- **gas**

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

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

Distributed by:

Major® Pharmaceuticals

31778 Enterprise Drive

Livonia MI 48150 USA

EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Simethicone 125 mg softgels

MAJOR EXTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5458
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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	PO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5458-46	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	09/16/1998	

Labeler - Major Pharmaceuticals (191427277)