# GAS RELIEF EXTRA STRENGTH- 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.

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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.

#### **Directions**

- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours unless directed by a doctor

#### Other information

- store between 15-30°C (59-86°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, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

\*contains one or more of these ingredients

#### Questions or comments?

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

### **Principal Display Panel**

Compare to the active ingredient in Gas-X® Extra Strength<sup>†</sup>

Extra Strength

#### **Gas Relief**

Simethicone 125 mg

**Antigas** 

Fast relief of

- Pressure
- Bloating
- Discomfort

Small, easy to swallow

Softgels

<sup>†</sup>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.

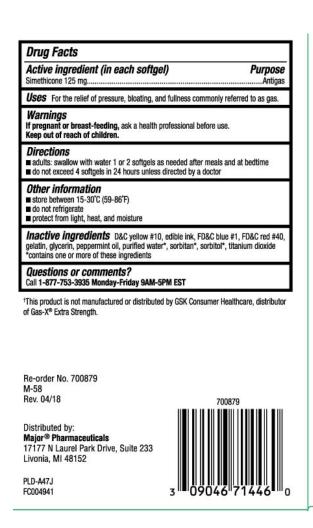
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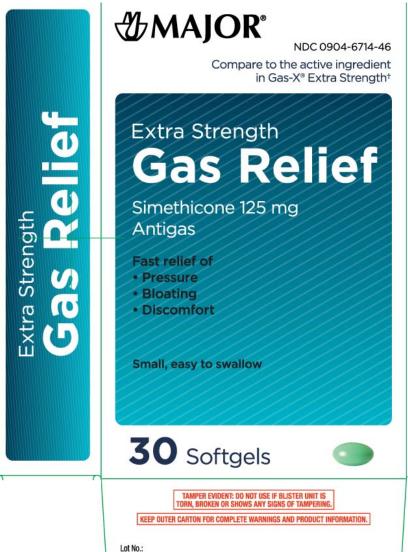
Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

#### **Product Label**





#### **MAJOR Extra Strength Gas Relief**

Exp. Date:

#### GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6714
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	9mm	
Flavor		Imprint Code	PO;SCU;L125	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0904-6714- 46	30 in 1 CARTON	03/31/2018	03/31/2025	
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	part332	03/31/2018	03/31/2025

## Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2022 Major Pharmaceuticals