GAS RELIEF- simethicone 180 mg capsule, liquid filled We Care Distributor 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.

Gas Relief - Simethicone 180 mg

Drug Facts

Active ingredient (in each softgel)

Purpose

Simethicone 180 mg...... Antigas

Uses

for relief of

■ pressure, bloating, and fullness commonly referred to as gas

Warnings

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 2 softgels in 24 hours except under the advice and supervision of a physician

Other information

- store at controlled room temperature 20°-25°C (68°-77°F).
- protect from moisture
- read all product information before using.
- keep this box for important information

Inactive ingredients

FD&C yellow 6, gelatin, glycerin, hypromellose, peppermint oil, purified water, sorbitol, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

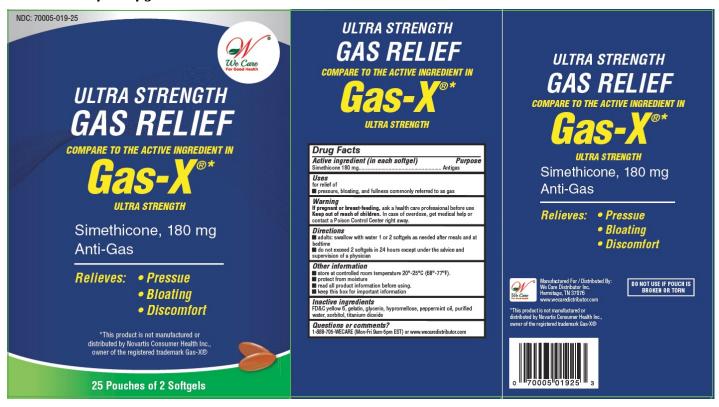
PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredients in Gas-X Ultra Strength

Simethicone Softgels, 80 mg

TO OPEN PUSH IN TAB AND PULL OUT

25 Pouches of 2 Softgel Each



GAS RELIEF

simethicone 180 mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-019
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
PEPPERMINT OIL (UNII: AV092KU4JH)				

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WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	10 mm
Flavor		Imprint Code	P10
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70005-019-25	25 in 1 BOX			
1		2 in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:70005-019-50	50 in 1 BOX			
2		2 in 1 POUCH; Type 0: Not a Combination Product			
3	NDC:70005-019-02	2 in 1 POUCH			
3		2 in 1 POUCH; 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	10/01/2009	

Labeler - We Care Distributor Inc. (079832998)

Establishment				
Name	Address	ID/FEI	Business Operations	
SOFTGEL HEALTHCARE PVT LTD		675584180	manufacture(70005-019)	

Revised: 3/2016 We Care Distributor Inc.