GAS-X EXTRA STRENGTH SOFTGELS- simethicone capsule, liquid filled GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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

Antigas

Use

for the relief of

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

Warning

Keep out of reach of children.

Directions

- adults and children 12 years and older: 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 20-25°C (68-77°F)
- protect from light, heat, and moisture

Inactive ingredients

D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, glycerin, hypromellose, mannitol, medium chain triglycerides, peppermint oil, propylene glycol, purified water, sorbitol, soy lecithin, titanium dioxide

Questions or comments?

1-855-328-5204

Additional information

Gas-XExtra Strength Softgels offer fast, effective relief of pressure and bloating that antacids can't provide. They are specially formulated with simethicone, the antigas medicine doctors recommend most for pressure, bloating, or discomfort referred to as gas.

READ ALL PRODUCT INFORMATION BEFORE USING.

KEEP CARTON FOR IMPORTANT INFORMATION.

Gas-XExtra Strength Softgels are concentrated to contain liquid gas-fighting medicine in a small softgels so they are easy to swallow, and there is no chalky taste.

TAMPER EVIDENT FEATURE:

Do not use if blister is broken or damaged.

1-855-328-5204

Distributed by:

GSK Consumer Healthcare

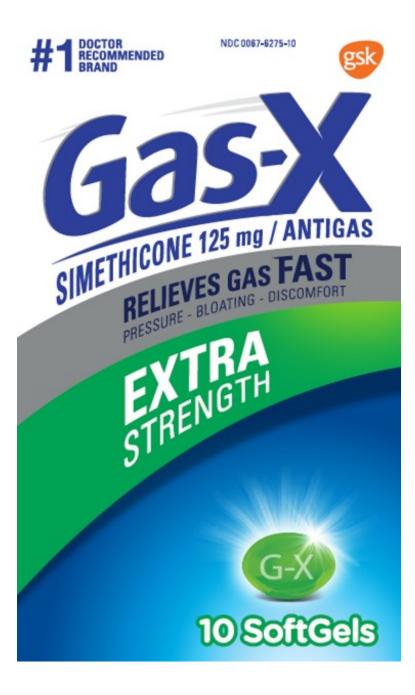
Warren, NJ 07059

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Principal Display Panel NDC 0067-6275-10 #1 DOCTOR RECOMMENDED BRAND Gas-X SIMETHICONE 125 mg / ANTIGAS RELIEVES GAS FAST PRESSURE – BLOATING – DISCOMFORT EXTRA STRENGTH G-X 10 SoftGels

6200000047349 - Front Carton



GAS-X EXTRA STRE		S			
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:0067-6275	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingre	dient Name		Basis of St	rength	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: WZ B9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 30WL53L36A)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	G;X
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067- 6275-30	3 in 1 CARTON	09/12/2011	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0067- 6275-10	1 in 1 CARTON	09/12/2011	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0067- 6275-20	2 in 1 CARTON	09/12/2011	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0067- 6275-50	5 in 1 CARTON	09/12/2011	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:0067- 6275-72	6 in 1 CARTON	09/12/2011	
5		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:0067- 6275-82	10 in 1 CARTON	09/12/2011	11/23/2019
6		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:0067- 6275-01	120 in 1 CARTON; Type 0: Not a Combination Product	08/01/2017	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part332	09/12/2011			

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 7/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC