ULTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled Wal-Mart Stores 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.

Ultra Strength Gas Relief

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Antigas

Use

for the relief of

• pressure and bloating commonly referred to as gas

Warnings

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 2 softgels in 24 hours 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
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

FD&C yellow#6, gelatin, glycerin, purified water and white ink

Questions or comments?

Call toll free: **1-888-287-1915**

PRINCIPAL DISPLAY PANEL

Ultra Strength Gas Relief

Simethicone 180 mg Anti-gas 50 Softgels

NDC 49035-585-21

*Compare to the active ingredient in Gas- $X^{\ensuremath{\mathbb{R}}}$ Ultra Strength



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Question or comments? Call toll free: 1-888-287-1915 *This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Gas-X® Ultra Strength Softgels.

ULTRA STRENGTH GAS RELIEF

at bedtime

I do not exceed 2 softgels in 24 hours

except under the advice and

supervision of a physician

simethicone capsule, liquid filled

softgels as needed after meals and

adults: swallow with water 1 or 2

Directions

Iruq Facts (continued

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-585
Route of Administration	ORAL		

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

Inactive Ingredients				
Ingredient Name	Strength			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	orange (clear)	Score	no score
Shape	capsule (oval)	Size	10 mm
Flavor		Imprint Code	PC3
Contains			

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:49035-585-21	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/24/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	10/24/2017	

Labeler - Wal-Mart Stores Inc (051957769)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(49035-585), analysis(49035-585)

Revised: 10/2017 Wal-Mart Stores Inc