GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled United Natural Foods, Inc. dba UNFI

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

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 except under the advice and supervision of a physican

Other information

- store between 20-25°C (68-77°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, mannitol, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call toll free 1-855-423-2630

Principal Display Panel

Compare to Gas-X® Extra Strength active ingredient†

extra strength

gas relief

simethicone 125 mg

(antigas)

relief of

- bloating
- pressure
- discomfort

softgels

†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.

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908

Product Label



extra strength

gas relief

NDC 41163-597-30 compare to Gas-X® Extra Strength active ingredient[†]



30 softgels

actual size

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.
PI D-C597A FC008737

Lot No.:

Exp. Date:

EQUALINE Extra Strength Gas Relief

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Like it or let us make it right. **That's our quality promise.** 855-423-2630

PRODUCT OF INDIA

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-597 Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of 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)	
MANNITOL (UNII: 30WL53L36A)	

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41163-597- 30	30 in 1 CARTON	11/29/2019			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:41163-597- 50	50 in 1 CARTON	11/29/2019			
2		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	part347	11/29/2019			

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 7/2023 United Natural Foods, Inc. dba UNFI