

**WINCO FOODS GAS RELIEF EXTRA STRENGTH SOFTGELS-
simethicone capsule, liquid filled
WinCo Foods, 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 125mg

Purpose

Antigas

Use

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 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 10, FD&C blue 1, FD&C red 40, gelatin, glycerin, hypromellose, peppermint oil, sorbitan, sorbitol, titanium dioxide

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-379
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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: WZB9127XOA)	
GELATIN TYPE B BOVINE (230 BLOOM) (UNII: WML1404U79)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	SCU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-379-30	2 in 1 CARTON	12/02/2020	
1		15 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	12/02/2020	

Labeler - WinCo Foods, LLC (056098817)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss Caps Romania		565466997	manufacture(67091-379)

Revised: 12/2022

WinCo Foods, LLC