

**CAREONE EXTRA STRENGTH GAS RELIEF - simethicone tablet, chewable
Retail Business Services, 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.

Extra Strength Gas Relief Tablets

ACTIVE INGREDIENT(in each tablet)

Simethicone 125 mg

PURPOSE

Anti-gas

USE(S)

relieves:

- pressure
- bloating
- symptoms referred to as gas

WARNINGS

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KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a poison control center immediately.

DIRECTIONS

- chew 1 to 2 tablets thoroughly as needed after meals and at bedtime
- do not exceed 4 tablets in a 24 hour period except under the advice and supervision of a physician

OTHER INFORMATION

- do not use if any individual blister unit is broken or open
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

INACTIVE INGREDIENTS

D&C red # 30 aluminum lake, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose

PRINCIPAL DISPLAY PANEL

NDC 72476-019-73

Careone

Compare to the Active Ingredient in Gas-X® Chewables Extra Strength*

EXTRA STRENGTH GAS RELIEF

Simethicone 125 mg - Anti-Gas

Cherry Creme

FAST RELIEF OF:

- DISCOMFORT FROM GAS
- BLOATING
- PRESSURE

18 chewable tablets



CAREONE EXTRA STRENGTH GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-019
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 RED NO. 30 (UNII: 2S42T2808B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	14mm
Flavor	CHERRY	Imprint Code	G134
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-019-73	3 in 1 CARTON	10/13/2021	
1		6 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	10/13/2021	

Labeler - Retail Business Services, LLC. (967989935)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(72476-019)

Revised: 9/2018

Retail Business Services, LLC.