

GAS RELIEF - simethicone tablet, chewable
Topco Associates, 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.

Topco 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

GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-122
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: 70097M6I3O)	
CELLULOSE, MICROCRYSTALLINE (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:36800-122-73	3 in 1 CARTON	09/28/2018	
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	09/28/2018	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(36800-122)

Revised: 9/2018

Topco Associates, LLC