

GAS RELIEF- simethicone tablet, chewable

Safeway

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 Peppermint Tablets

Active ingredient (in each tablet)

Simethicone 125 mg

Purpose

Anti-gas

Uses

relieves:

- pressure
- bloating
- symptoms referred to as gas

Warnings

Keep out of the 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 40oC (104oF)

Inactive ingredients

D&C red 30 aluminum lake, D&C yellow 10 aluminum lake, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose

PDP

*Compare to GAS-X®E-X Chewable active ingredient

Signature Care

Extra strength Gas Relief

Simethicone 125 mg

Anti-Gas

Peppermint Flavor

Relieves symptoms of gas discomfort, pressure and bloating

18 chewable tablets



GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-135
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
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D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTROSE (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	16 mm
Flavor	PEPPERMINT	Imprint Code	G134
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-135-73	2 in 1 CARTON	11/11/2015	
1		9 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	11/11/2015	

Labeler - Safeway (009137209)

Registrant - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(21130-135)