HEB GAS RELIEF EXTRA STRENGTH PEPPERMINT - simethicone tablet, chewable H E B

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.

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

PRINCIPAL DISPLAY PANEL

*Compare to Gas-X® EX chewables active ingredient NDC 37808-155-73 **HEB**

Extra strength

Gas

Relief

Simethicone 125 mg

Anti-Gas

Fast Relief of:

- Symptoms Referred to as Gas
- Discomfort
- Pressure
- Bloating

Peppermint Flavor

18 chewable tablets



HEB GAS RELIEF EXTRA STRENGTH PEPPERMINT

simethicone tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-155
Route of Administration	ORAL		

	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
l	DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg		

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 30 (UNII: 2S42T2808B)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
SORBITOL (UNII: 506T60A25R)			
SUCROSE (UNII: C151H8M554)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)			

Product Characteristics				
Color	YELLOW	Score	no score	
Shape	ROUND	Size	14mm	
Flavor	PEPPERMINT	Imprint Code	G134	
Contains				

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:37808-155-73	2 in 1 CARTON	09/28/2018	
ı	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	09/28/2018		

Labeler - HEB (007924756)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(37808-155)	

Revised: 9/2018 HE B