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

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

PRINCIPAL DISPLAY PANEL

Topcare NDC 36800-122-73 **COMPARE TO GAS-X® EXTRA STRENGTH ACTIVE INGREDIENT*** EXTRA STRENGTH Gas Relief ANTI-GAS/SIMETHICONE, 125 mg

FAST RELIEF OF:

- Bloating
- Pressure
- Discomfort of Gas

CHERRY FLAVOR

18 CHEWABLE TABLETS

		+TopCare, health Gas Relief ANTI-GAS/SIMETHICONE, 125 mg
Drug Facts Active ingredient (in each tablet) Purpose Simethicone 125 mg Anti-gas Uses relieves: pressure bloating symptoms referred to as gas Marings Gondard 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 sore at room temperature a wold high humidity and excessive head, above 40°C (100+T) Intertive Ingredients D&C root 2000 Centrol Centrol Centrol Sore at room temperature a wold high humidity and excessive head, above 40°C (100+T) Intertive Ingredients D&C root 2000 Centrol Centrol Sore at room temperature cellulose, sorbitol, sucrose. DISTRBUTED BY TOPCO ASSOCHTES LLE LK GROVE VILAGE, IL GOOT Gondard 200 GUAX321 QUESTIONS? 1-888-423-0133 toperate/btopco. Sore 100 GUAX321 QUESTIONS? 1-888-423-0133 toperate/btopco. Strated to guarante its highest quality. You total satisfaction is guaranteed. Not sets 4-23-0133 toperate/btop duality. Sore 100 GUAX321 QUESTIONS? 1-888-423-0133 toperate/btop duality. Heath, Inc., the distibutor of gas-X@ Extra Strength. Not set 4-23-0132 toperate/btop duality. Sore 100 Guata21-90 Guata21-90 Guata21-90 Guata21-90 Guata21-90 Guata21-90	 TopCare. EXTRA STRENGTH health Gas Relief ANTI-GAS/SIMFIHICONE, 125 mg 	<text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text>

Product Info	rmation							
Product Type		HUMAN OTC E	DRUG	ltem C	ode (So	ource)	NDC:368	300-122
Route of Admir	nistration	ORAL						
Active Ingred	dient/Activ	ve Moiety						
Ingredient Name					Basis of Strength		Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETHICONE							125 mg	
Inactive Ingr	edients							
		Ingredier	nt Name				S	trength
D&C RED NO. 30	(UNII: 2S42T2	2808B)						
MAGNESIUM STE	ARATE (UNII:	70097M6I30)						
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)								
SORBITOL (UNII:	SORBITOL (UNII: 506T60A25R)							
SUCROSE (UNII: C								
	,151000554)							
MALTODEXTRIN	(UNII: 7CVR7L4		35W2)					
MALTODEXTRIN DEXTROSE, UNSI	(UNII: 7CVR7L4 Pecified fo	RM (UNII: IY9XDZ:	35W2)					
MALTODEXTRIN DEXTROSE, UNSI Product Chai	(UNII: 7CVR7L4 PECIFIED FO racteristic	rm (UNII: IY9XDZ : :S					no score	
MALTODEXTRIN DEXTROSE, UNSI Product Cha i Color	(UNII: 7CVR7L4 PECIFIED FO racteristic P	rm (Unii: Iy9xdz: : S Ink	Score				no score	
MALTODEXTRIN DEXTROSE, UNSI Product Cha i Color Shape	(UNII: 7CVR7L4 PECIFIED FO racteristic P R	RM (UNII: IY9XDZ: S INK OUND	Score Size	Codo			14mm	
MALTODEXTRIN DEXTROSE, UNSI Product Cha i Color Shape Flavor	(UNII: 7CVR7L4 PECIFIED FO racteristic P R	rm (Unii: Iy9xdz: : S Ink	Score	Code				
MALTODEXTRIN DEXTROSE, UNSI Product Cha i Color Shape Flavor	(UNII: 7CVR7L4 PECIFIED FO racteristic P R	RM (UNII: IY9XDZ: S INK OUND	Score Size	Code			14mm	
MALTODEXTRIN DEXTROSE, UNSI Product Cha i Color Shape Flavor Contains	(UNII: 7CVR7L4 PECIFIED FO racteristic P R	RM (UNII: IY9XDZ: S INK OUND	Score Size	Code			14mm	
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging	(UNII: 7CVR7L4 PECIFIED FO racteristic P R C	RM (UNII: IY9XDZ: S INK OUND	Score Size Imprint (Code		eting Start Date	14mm G134 Marko	eting End Date
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging # Item Code	(UNII: 7CVR7L4 PECIFIED FO racteristic P R C	RM (UNII: IY9XDZ: S INK OUND HERRY Package Desc	Score Size Imprint (Date	14mm G134 Marko	-
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging # item Code 1 NDC:36800-122 73	(UNII: 7CVR7L4 PECIFIED FO racteristic P R C	RM (UNII: IY9XDZ: S INK OUND HERRY Package Desc	Score Size Imprint (Date	14mm G134 Marko	
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging # item Code 1 NDC:36800-122 73	(UNII: 7CVR7L4 PECIFIED FO P R R C C C C C C C C C C C C C C C C C	RM (UNII: IY9XDZ: S INK OUND HERRY Package Desc	Score Size Imprint (Date	14mm G134 Marko	-
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging # Item Code 1 NDC:36800-122 73	(UNII: 7CVR7L4 PECIFIED FO R R C R C R C S S S S S S S S S S S S S	RM (UNII: IY9XDZ: S INK OUND HERRY Package Desc ON TER PACK; Type 0:	Score Size Imprint (Date	14mm G134 Marko	-
MALTODEXTRIN DEXTROSE, UNSI Product Chai Color Shape Flavor Contains Packaging # Item Code	(UNII: 7CVR7L4 PECIFIED FO R C R R C C S S S S S S S S S S S S S S	RM (UNII: IY9XDZ: S INK OUND HERRY Package Desc ON TER PACK; Type 0:	Score Size Imprint (Not a Combined Not a Combined States of Monoger	nation	09/28/20	Date	14mm G134 Marke	

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

Revised: 9/2018

Topco Associates, LLC