RUGBY GAS RELIEF - simethicone tablet, chewable Rugby Laboratories

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.

Rugby Extra Strength Gas Relief Chewable 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

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 inner seal is broken
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

INACTIVE INGREDIENTS

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.

QUESTIONS OR COMMENTS?

1 (800) 645-2158

PRINCIPAL DISPLAY PANEL

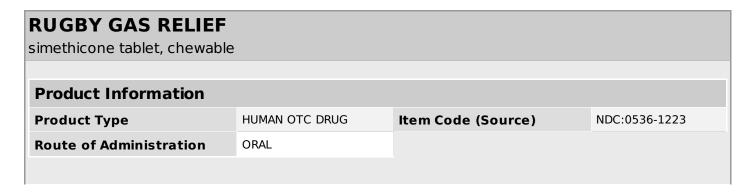
COMPARE TO ACTIVE INGREDIENT IN GAS-X® EXTRA STRENGTH* NDC 0536-1223-08 Rugby

EXTRA STRENGTH GAS

RELIEF LACTOSE FREE Simethicone 125 mg each Antiflatulent

60 CHEWABLE TABLETS





Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SUGARCANE (UNII: 81H2R5AOH3)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	16mm
Flavor	PEPPERMINT	Imprint Code	GDC131
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1223- 08	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	04/29/2019	

Labeler - Rugby Laboratories (079246066)

Establishment					
Name	Address	ID/FEI	Business Operations		
Guardian Drug Company		119210276	MANUFACTURE(0536-1223)		

Revised: 1/2022 Rugby Laboratories