

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 Gas Relief Chewable Tablets

ACTIVE INGREDIENT(in each tablet)

Simethicone 80 mg

PURPOSE

Antigas

USE(S)

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.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by 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

NDC 0536-1207-04

Rugby

GAS

RELIEF

LACTOSE FREE

Simethicone 80 mg each

ANTIFLATULENT

100 CHEWABLE TABLETS

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Drug Facts

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Distributed by:
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LOT: 3 05361 20704 5

EXP: 5

RUGBY GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1207
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
SUGARCANE (UNII: 81H2R5AOH3)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	G103
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1207-04	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	04/25/2019	

Labeler - Rugby Laboratories (079246066)**Establishment**

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(0536-1207)