GAS RELIEF MINT FLAVOR- simethicone tablet, chewable Raritan Pharmaceuticals Inc

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.

DRxCHOICE Simethicone Gas Relief 36 Chewable Tablets

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Antigas

Uses

Relieves:

- bloating
- pressure
- symptoms referred to as gas

Warnings

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center immediately at 1-800-222-1222.

Directions

- thoroughly chew 1 to 2 tablets as needed after meals and at bedtime
- do not exceed 4 tablets in 24 hours period except under the advice and supervision of a physician.

Other information

- store at room temperature 20-25°C (68-77°F)
- each tablets contains: calcium 60mg

Inactive ingredients

dextrose, peppermint flavor, magnesium stearate, maltodextrin, microcrystalline

Principal Display Panel

NDC 68163-111-36

DRx CHOICE

Gas Relief

Anti Gas/Simethicone 80 mg

For fast relief of Bloating, Pressure & Gas Distress

Mint Flavor

Naturally and Artificially Flavored

36 CHEWABLE TABLETS

Manufactured by: Raritan Pharmaceuticals

8 Joanna Court, East Brunswick, NJ 08816



Simethicone 36 Chewable Tablets

Froduct Information Product Type Route of Administration Active Ingredient/Active Moiety Ingredient Name HINT FLAVOR Simethicone tablet, chewable Item Code (Source) NDC:68163-111 Route Of Administration NDC:68163-111 Route of Administration NDC:68163-111 NDC:68163-111 Strength

DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	80 mg
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Inactive Ingredients		
Ingredient Name	Strength	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)		
PEPPERMINT (UNII: V95R5KMY2B)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)		

Product Character	duct Characteristics				
Color	WHITE	Score	no score		
Shape	ROUND	Size	13mm		
Flavor	PEPPERMINT	Imprint Code	RP111		
Contains					

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:68163- 111-36	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	04/17/2019	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023 Raritan Pharmaceuticals Inc