

SIMETHICONE 125 MG- simethicone tablet, chewable
Reliable 1 Laboratires 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.

Simethicone 125 mg

Drug Facts

Active ingredient (in each chewable tablet)

Simethicone 125 mg

Antiflatulent

Use

relieves bloating, pressure and fullness commonly referred to as gas

Warnings

Keep out of reach of children

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Directions

- thoroughly chew 1-2 tablets as needed after meals and at bedtime
- do not take more than 4 tablets per day

Other information

store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

compressible sugar, dextrose, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide, sorbitol, stearic acid

Questions or comments?

call **516-341-0666**, 8:30 am -4:30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Mylanta®

Distributed by: **Reliable 1 Laboratories LLC**

Valley Stream, NY 11580

www.reliable1labs.com

NDC 69618-032-06

Simethicone 125 mg

ANTIFLATULENT

60 CHEWABLE TABLETS

*Compare to Active Ingredient in MYLANTA® GAS MAXIMUM STRENGTH

60 CHEWABLE TABLETS

Simethicone
125 mg
ANTIFLATULENT

Reliable-1
LABORATORIES

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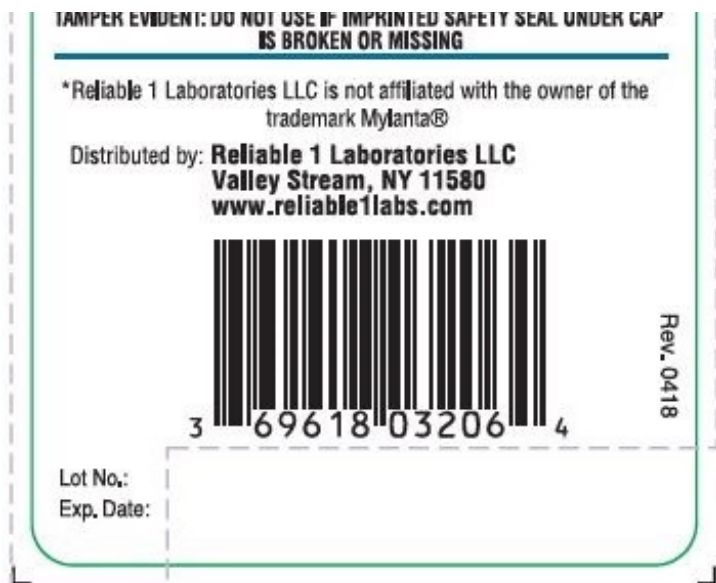
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SIMETHICONE 125 MG

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-032
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEPPERMINT (UNII: V95R5KMY2B)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DEXTROSE (UNII: IY9XDZ35W2)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white (Off white)	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor		Imprint Code	AP;040
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-032-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	04/25/2018	

Labeler - Reliable 1 Laboratoires LLC (079718111)**Registrant** - Simethicone 125 mg (079718111)

Revised: 3/2023

Reliable 1 Laboratoires LLC