

SIMETHICONE 80 MG- simethicone tablet, chewable
Reliable 1 Laboratories 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 80 mg

Drug Facts

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 6 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 to 4:30 pm ET, Monday - Friday

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

Distributed by: **Reliable 1 Laboratories LLC**

Valley Stream, NY 11580

www.reliable1labs.com

Active ingredient (in each chewable tablet)

Simethicone 80 mg

Purpose

Antiflatulent

NDC 69618-033-01

Simethicone 80 mg

ANTIFLATULENT

100 CHEWABLE TABLETS



Drug Facts

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|--|----------------|
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SIMETHICONE 80 MG

simethicone tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69618-033 |
| 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 |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| SORBITOL (UNII: 506T60A25R) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCROSE (UNII: C151H8M554) | |
| DEXTROSE (UNII: IY9XDZ35W2) | |
| PEPPERMINT (UNII: V95R5KMY2B) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | white (Off White) | Score | no score |
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | AP;019 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69618-033-01 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/24/2018 | |



SIMETHICONE 80MG CHEW TABLET

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part332 | 04/24/2018 | |

Labeler - Reliable 1 Laboratories LLC (079718111)

Registrant - Reliable 1 Laboratories LLC (079718111)