

SIMETHICONE 80 MG- simethicone tablet, chewable
A-S Medication Solutions

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

Keep out of reach of children

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

HOW SUPPLIED

Product: 50090-5431

NDC: 50090-5431-3 30 TABLET, CHEWABLE in a BOTTLE

SIMETHICONE 80 MG (SIMETHICONE) TABLET, CHEWABLE



SIMETHICONE 80 MG

simethicone tablet, chewable

Product Information

| | | | |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-5431(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 |
|---|----------|
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| SORBITOL (UNII: 506T60A25R) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCROSE (UNII: C151H8M554) | |
| DEXTROSE, UNSPECIFIED FORM (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:50090-5431-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 01/13/2021 | |



Marketing Information

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

Labeler - A-S Medication Solutions (830016429)

| Establishment | | | |
|--------------------------|----------------|---------------|--|
| Name | Address | ID/FEI | Business Operations |
| A-S Medication Solutions | | 830016429 | RELABEL(50090-5431) , REPACK(50090-5431) |

Revised: 1/2021

A-S Medication Solutions