

SIMETHICONE 80MG- simethicone tablet, chewable
Cardinal Health 107, LLC

SIMETHICONE 80 mg CHEWABLE TABLETS

ACTIVE INGREDIENT (IN EACH TABLET)

SIMETHICONE 80MG

PURPOSE

ANTI-GAS

USES

- RELIEVES GAS DISTRESS, BLOATING, AND DISCOMFORT

WARNINGS

- GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY AT 1-800-222-1222.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

- **ADULTS** CHEW 1 OR 2 TABLETS COMPLETELY AS NEEDED AFTER MEALS AND AT BEDTIME. DO NOT SWALLOW TABLETS WHOLE.
- DO NOT EXCEED 6 TABLETS IN 24 HOUR PERIOD EXCEPT UNDER THE ADVICE AND SUPERVISION OF A PHYSICIAN.

OTHER INFORMATION

- EACH TABLET CONTAINS: CALCIUM 60MG
- STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

DEXTROSE, FLAVOR, MAGNESIUM STEARATE, MALTODEXTRIN, MICROCRYSTALLINE CELLULOSE, SILICA, TRIBASIC CALCIUM PHOSPHATE

Generic Section

Distributed by:

GenDose Pharmaceuticals

Huntersville, NC 28078

Distributed By:

Cardinal Health

Dublin, OH 43017

L58749200924

Principal Display Panel

Simethicone 80mg

Chewable Tablets

10 Chewable Tablets



E114

NDC 55154-2606-0

**SIMETHICONE 80mg
CHEWABLE TABLETS**

10 CHEWABLE TABLETS

Mint Flavor

Anti-gas for Fast-acting relief of

- Bloating • Pressure • Discomfort of gas

Drug Facts

Active Ingredient (in each tablet)

Simethicone 80mg

Purpose

Anti-gas

INACTIVE INGREDIENTS:

dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, silica, tribasic calcium phosphate

USES:

- relieves gas distress, bloating and discomfort

DIRECTIONS:

- Adults chew 1 or 2 tablets completely as needed after meals and at bedtime, Do not swallow tablets whole.
- Do not exceed 6 tablets in 24 hour period except under the advice and supervision of a physician.

OTHER INFORMATION:

- each tablet contains: calcium 60 mg

STORAGE: Store at room temperature

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

Keep this and all drugs out of the reach of children.

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

GenDose®

Pharmaceuticals

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Lot: Exp:

SIMETHICONE 80MG

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-2606(NDC:77333-812)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	15mm
Flavor		Imprint Code	RP111
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-2606-0	10 in 1 BAG	10/01/2024	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	10/01/2024	

Labeler - Cardinal Health 107, LLC (118546603)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	REPACK(55154-2606)

Revised: 10/2024

Cardinal Health 107, LLC