

SIMETHICONE 80MG- simethicone tablet, chewable
Gendose Pharmaceuticals, LLC

GENDOSE - SIMETHICONE 80 mg CHEWABLE TABLETS (77333-812)

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

NDC 77333-812-10

Simethicone 80mg Chewable Tablets

Mint Flavor

Anti-gas for Fast-acting relief of:

- Bloating • Pressure • Discomfort of gas

UD 100 Tablets (10x10)



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Anti-gas for Fast-acting relief of:

- Bloating • Pressure • Discomfort of gas

UD 100 Tablets (10x10)

Drug Facts

Active ingredient (in each tablet)	Purpose
Simethicone 80mg.....	Anti-gas

Uses:

- relieves gas distress, bloating, and discomfort

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:

- **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

LB81210X09

SIMETHICONE 80MG

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-812
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
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
DEXTROSE (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:77333-812-10	100 in 1 BOX	10/15/2022	
1	NDC:77333-812-25	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	09/02/2022	

Labeler - Gendose Pharmaceuticals, LLC (080257510)

Revised: 1/2024

Gendose Pharmaceuticals, LLC