

SIMETHICONE- simethicone tablet, chewable
Aphena Pharma Solutions - Tennessee, LLC

gc 791

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Anti-Gas

Uses

relieves pressure, bloating, and fullness
commonly referred to as gas

Warnings

If pregnant or breast feeding,ask a health professional before use.

Keep out of reach of children.

Directions

- chew or crush tablet completely before swallowing
- adults and children 12 years and over: take 1-2 tablets as needed after meals and at bedtime.

Do not exceed 6 tablets in 24 hours except under the advice and supervision of a doctor.

- children under 12 years: ask a doctor

Other information

- each tablet contains: **calcium 65 mg**
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken
- store at room temperature, 15°C - 30°C (59°F - 86°F)
- protect from moisture

HOW SUPPLIED

Simethicone Chewable Tablets, 80 mg are white, round, tablets, debossed with "44 & 137" on one side and are supplied as:

NDC 57896-791-01 in bottle of 100 chewable tablets

NDC 57896-791-08 in bottle of 80 chewable tablets

Distributed by:

GERI-CARE Pharmaceuticals Corp.

1650 63rd Street, Brooklyn, NY 11204

Inactive ingredients

cellulose, corn starch, crospovidone, dextrates hydrated, flavor, magnesium stearate, silica, sucralose, calcium phosphate.

Questions or comments?

1-800-540-3765

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	80 mg
4	71610-649-04

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20220519JK

PRINCIPAL DISPLAY PANEL - 80 mg

NDC 71610-649 - Simethicone 80 mg Chewable Tablet - Rx Only

Simethicone

80mg 4 Chewable Tablets

NDC# 71610-0649-04

Store between 20-25 degrees C(68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a tight light-resistant container
as defined by USP.
Keep this and all drugs out of the reach of children
MFG BY: Geri-Care Pharmaceuticals Corp.
Brooklyn, NY
RPMG BY: Aphenix Pharma, Cookeville, TN 38506

Simethicone

80mg 4 Chewable Tablets

71610-0649-04

MFG LOT: 12345
GTIN 10371610649048
S/N P84701
BATCH M39782
EXP 12/2024

SIMETHICONE				
simethicone tablet, chewable				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:71610-649(NDC:57896-791)	
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)				
DEXTRATES (UNII: G263MI44RU)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)				
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPVIDONE (UNII: 2S7830E561)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	PEPPERMINT	Imprint Code	44;137	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-649-	4 in 1 BOTTLE; Type 0: Not a Combination	05/10/2022	

04	Product	03/19/2022	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	01/01/2004	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	repack(71610-649)

Revised: 1/2025

Aphena Pharma Solutions - Tennessee, LLC