

**SIMETHICONE- simethicone tablet, chewable**  
**Aphena Pharma Solutions - Tennessee, 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.*

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**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 Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

<b>Count</b>	<b>80 mg</b>
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: Gerl-Care Pharmaceuticals Corp.  
Brooklyn, NY  
RPKG BY: Aphena Pharma, Cookeville, TN 38506  
MFG LOT: 12E45  
GTIN 10373610649048  
S/N P84701  
BATCH M199782  
EXP 12/2024

**SIMETHICONE**

simethicone tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71610-649(NDC:57896-791)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>DEXTRATES</b> (UNII: G263MI44RU)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TRICALCIUM PHOSPHATE</b> (UNII: K4C08XP666)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	44;137
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:71610-649-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2022	
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/01/2004	

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

## Establishment

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

Revised: 6/2022

Aphenia Pharma Solutions - Tennessee, LLC