# 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 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.

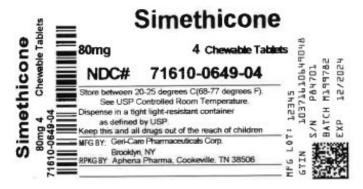
Repackaged by:



Cookeville, TN 38506

20220519JK

**PRINCIPAL DISPLAY PANEL - 80 mg** 



# **SIMETHICONE**

simethicone tablet, chewable

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71610-649(NDC:57896-791)

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
mgreateric riame	basis of strength	July 111
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	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)		
CROSPOVIDONE (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			

P	ackaging			
#	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	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph fina	part332	01/01/2004	

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-649)	

Revised: 6/2022 Aphena Pharma Solutions - Tennessee, LLC