# 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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#### **GAS RELIEF SIMETHICONE**

#### **Drug Facts**

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# Active Ingredient (in each chewable tablet)

Simethicone 80 mg

### **Purpose**

**Antiflatulent** 

#### Uses

relieves

- bloating
- pressure
- discomfort of gas which can be caused by certain foods or air swallowing

## **Warnings**

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

## Keep out of reach of children

#### **Directions**

- chew thoroughly 1 to 2 tablets as needed after meals and at bed time.
- do not exceed 6 tablets per day unless directed by a doctor

#### Other Information

- store at room temperature 15-30 °C (59-86 °F)
- protect from moisture

#### **Inactive Ingredients**

dextrose, dipac sugar, maltodextrin, peppermint flavor, sorbitol, stearic acid

#### **Questions or Comments**

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Call 804-270-4498, 8.30 am - 4.30 pm EST Monday - Friday

#### **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	71610-607-04

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:

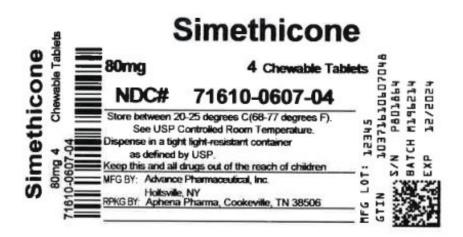


Cookeville, TN 38506

20211105JH

## PRINCIPAL DISPLAY PANEL - 80 mg

NDC 71610-607 - Simethicone 80 mg Chewable Tablets



#### **SIMETHICONE**

simethicone tablet, chewable

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:71610-607(NDC:54738-518)

Route of Administration ORAL

**Active Ingredient/Active Moiety** 

Ingredient Name

Basis of Strength

DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)

DIMETHICONE

80 mg

Inactive Ingredients

Ingredient Name
Strength

DEXTROSE (UNII: IY9XDZ35W2)

SUCROSE (UNII: C151H8M554)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

PEPPERMINT (UNII: V95R5KMY2B)

SORBITOL (UNII: 506T60A25R)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	PEPPERMINT	Imprint Code	AP;019	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2021	
M	arketing I	nformation		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТ	C monograph fina	l part332	03/01/2011	

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

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-607)		

Revised: 11/2021 Aphena Pharma Solutions - Tennessee, LLC