

**ANTIFLATULENT - 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.*

-----  
**Major Simethicone**

**ACTIVE INGREDIENT(in each tablet)**

Simethicone 80 mg

**PURPOSE**

Antigas

**USE(S)**

relieves:

- pressure
- bloating
- symptoms referred to as gas

**WARNINGS**

.

**KEEP OUT OF REACH OF CHILDREN**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

**DIRECTIONS**

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by a physician

**OTHER INFORMATION**

- do not use if inner seal is broken
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

**HOW SUPPLIED**

Simethicone Chewable Tablets, 80 mg are white, round, tablets, debossed with "G and 103" on one side and are supplied as:

NDC 0904-7206-60 in bottle of 100 chewable tablets

Distributed by:

Major Pharmaceuticals

Livonia, MI 48152

## **INACTIVE INGREDIENTS**

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.

## **QUESTIONS**

Call (800) 616-2471

## **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	71610-650-04

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 71610-650 - Simethicone 80 mg Chewable Tablet - Rx Only

**Simethicone**  
80mg 4 Chewable Tablets

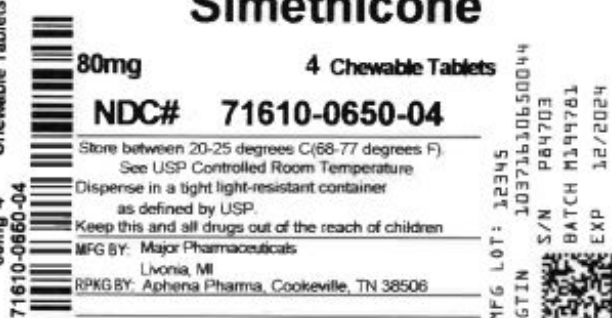
**80mg**      **4 Chewable Tablets**

**NDC# 71610-0650-04**

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: Major Pharmaceuticals  
Livonia, MI  
RPKG BY: Aphenix Pharma, Cookeville, TN 38506

MFG LOT: 122945  
GTIN 10971610650044  
S/N P84703  
BATCH M144781  
EXP 12/2024



## ANTIFLATULENT

simethicone tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71610-650(NDC:0904-7206)
<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>SUGARCANE</b> (UNII: 81H2R5AOH3)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### 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>	G;103
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-650-04	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 FINAL	part332	10/04/2021	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-650)

Revised: 6/2022

Aphenia Pharma Solutions - Tennessee, LLC