

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

Major Simethicone

ACTIVE INGREDIENT(in each tablet)

Simethicone 80 mg

PURPOSE

Antigas

USE(S)

relieves:

- pressure
- bloating
- symptoms referred to as gas

WARNINGS

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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:

Count	80 mg
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

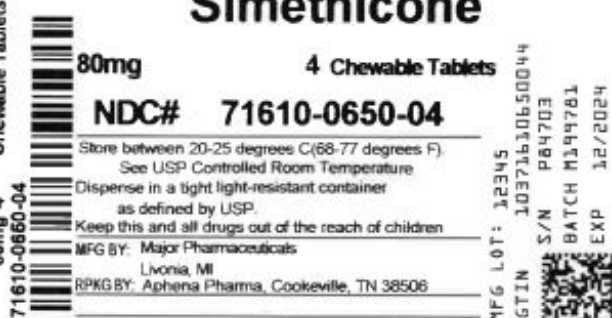
80mg **4 Chewable Tablets**

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: Aphenia Pharma, Cookeville, TN 38506

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



ANTIFLATULENT

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-650(NDC:0904-7206)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
SUGARCANE (UNII: 81H2R5AOH3)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	G;103
Contains			

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 Drug	M002	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: 1/2025

Aphenia Pharma Solutions - Tennessee, LLC