

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.

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 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	71610-607-04

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

80mg 4 Chewable Tablets

NDC# 71610-0607-04

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: Advance Pharmaceutical, Inc.
Holtsville, NY
RPKG BY: Aphenra Pharma, Cookeville, TN 38506

MFG LOT: 12345
GTIN 30371610607048
S/N P803664
BATCH M196214
EXP 12/2024



SIMETHICONE

simethicone tablet, chewable

Product Information

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	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	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	NDC:71610-607-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	10/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/01/2011	

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

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-607)

Revised: 11/2021

Aphenia Pharma Solutions - Tennessee, LLC