

MI-ACID GAS RELIEF - 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.

Mi-Acid Gas Relief

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Antigas

Enter section text here

Uses

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 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 40⁰C (104⁰F)

Inactive ingredients

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

Questions

To Report Adverse Drug Event 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	43353-325-04

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

20171030JH

PRINCIPAL DISPLAY PANEL - 80mg

NDC 43353-325 Simethicone 80mg - Rx Only



MI-ACID GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43353-325(NDC:0904-5068)
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
SUCROSE (UNII: C151H8M554)	
DEXTROSE (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	GDC103
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43353-325-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/02/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(43353-325)

Revised: 10/2017

Aphena Pharma Solutions - Tennessee, LLC