PLUSPHARMA- simethicone tablet, chewable Proficient Rx LP

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.

Drug Facts

Active ingredient (in each tablet)

Simethicone 80 mg, USP

Purpose

Anti-Gas

Uses

Relieves bloating and pressure commonly referred to as gas.

Warnings

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

Keep this and all drugs out of the reach of children.

Directions

- Adults: Chew 1 or 2 tablets as needed after meals and at bedtime.
- Do not exceed 6 tablets per day except under the advice and supervision of a physician.

Other Information

- Store at room temperature.
- Avoid high humidity.
- Do not use if imprinted safety seal under cap is broken or missing.

Inactive ingredients

Fructose, Maltodextrin, Natural and Artificial Spearmint Flavor, Silicon Dioxide, Sorbitol, Starch and Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Principal Display Panel

PlusPHARMA

SIMETHICONE 80 mg

ANTI GAS

Acts Fast to Relieve:

- Bloating
- Discomfort
- Pressure

Compare to the Active Ingredient in Gas-X® Chewables.

This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Gas-X® Chewables.

100 CHEWABLE TABLETS 80mg Each

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320





NDC 63187-516-00

Lot #:00000 Exp. 00/00/00 SN# MASTER

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Simethicone 80mg

#100

Chewable Tablets

Each tablet contains: Simethicone 80mg, USP Anti-Gas

White, round unscored tablet with imprint code "GPI; LB"

Product ID: RS051600

Dist. By: Plus Pharma, Commack, NY 11725

Store at room temperature.

Keep medication out of the reach of children

PLUSPHARMA

simethicone tablet, chewable

P	rod	luct	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-516(NDC:51645-860)

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients			
Ingredient Name	Strength		
FRUCTOSE (UNII: 6 YSS42VSEV)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SORBITOL (UNII: 506T60A25R)			
STARCH, CORN (UNII: O8232NY3SJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	white Score no		no score
Shape	ROUND (Round Flat Faced Beveled Edge)	Size	13mm
Flavor SPEARMINT (Natural and Artificial)		Imprint Code	GPI;LB
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:63187-516-	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 18		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/27/2006	

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	REPACK(63187-516), RELABEL(63187-516)	

Revised: 1/2021 Proficient Rx LP