PLUSPHARMA- simethicone tablet, chewable NuCare Pharmaceuticals, Inc.

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.

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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.



PLUSPHARMA

simethicone tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66267-643(NDC:51645-860)

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETHICO NE (UNII: 92RU3N3Y1O)

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 score
Shape	ROUND (Round Flat Faced Beveled Edge)	Size	13mm
Flavor	SPEARMINT (Natural and Artificial)	Imprint Code	GPI;LB

Contains

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66267-643-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2018	
2	NDC:66267-643-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2018	
3	NDC:66267-643-02	2 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2018	
4	NDC:66267-643-98	360 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2018	

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

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(66267-643)

Revised: 1/2021 NuCare Pharmaceuticals,Inc.