SIMETHICONE- 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.

gc 791

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Anti-Gas

Uses

relieves pressure, bloating, and fullness commonly referred to as gas

Warnings

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

Keep out of reach of children.

Directions

- chew or crush tablet completely before swallowing
- adults and children 12 years and over: take 1-2 tablets as needed after meals and at bedtime.

Do not exceed 6 tablets in 24 hours except under the advice and supervision of a doctor.

children under 12 years: ask a doctor

Other information

- each tablet contains: calcium 65 mg
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken
- store at room temperature, 15°C 30°C (59°F 86°F)
- protect from moisture

Inactive ingredients

cellulose, corn starch, crospovidone, dextrates hydrated, flavor, magnesium stearate, silica, sucralose, calcium phosphate.

Questions or comments?

1-800-540-3765

package Label



SIMETHICONE

simethicone tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-2746(NDC:57896-791)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	80 mg

Inactive Ingredients			
Ingredient Name	Strength		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
DEXTRATES (UNII: G263MI44RU)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSPOVIDONE (UNII: 2S7830E561)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CUCDALOGE (LINII) OSKSLIO27 DA)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	44;137
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68071- 2746-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/01/2004	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-2746)

Revised: 6/2022 NuCare Pharmaceuticals,Inc.