

SIMETHICONE- simethicone tablet, chewable**Geri-Care Pharmaceuticals, Corp**

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

for the relief of

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

Warnings**When using this product** • do not take more than directed, except under the advice of a doctor**If pregnant or breast feeding**, ask a health professional before use.**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.**Directions**

- adults and children 12 years and over, chew 1-2 tablets as needed after meals and at bedtime
- chew thoroughly
- do not exceed 6 tablets in 24 hours
- children under 12 years, consult a doctor

Other information

- 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)

Inactive ingredients

dextrose, peppermint flavor, silica, sorbitol, stearic acid, talc, calcium phosphate.

package Label

GERICARE

NDC 57896-791-01

CHEWABLE

SIMETHICONE

TABLETS USP, 80mg
FOR GAS DISTRESS
MINT FLAVOR
100 Tablets
80 mg each



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REV 0916

Distributed By:
GERI-CARE Pharmaceuticals Corp.
1650 63rd Street, Brooklyn, NY 11204



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SIMETHICONE

simethicone tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-791
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)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SORBITOL (UNII: 506T60A25R)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TALC (UNII: 7SEV7J4R1U)			
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)			
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:57896-791-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part332		01/01/2004	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 12/2017

Geri-Care Pharmaceuticals, Corp