

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.

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Anti-Gas

Uses

For the relief of pressure and bloating 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.

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

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 over 12 years, 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

- store at room temperature, 15°C - 30°C (59°F - 86°F)
- package not child resistant

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



Drug Facts
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REV 1212
 Dist. BY: Geri-Care Pharmaceuticals Corp.
 1650 63rd Street, Brooklyn, New York 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		
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: 12/2013

Geri-Care Pharmaceuticals, Corp