EXTRA STRENGTH GAS RELIEF- 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.

GC691

Active ingredient (in each tablet)

Simethicone 125 mg

Purpose

Antigas

Use

for the relief of 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults: chew 1 or 2 tablets as needed after meals and at bedtime
- do not exceed 4 tablets in 24 hours except under the advice and supervision of a physician

Other information

- each tablet contains: calcium 89 mg
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken.
- store at controlled room temperature
- protect from moisture

Inactive ingredients

cherry flavor, D&C red #27 lake, D&C red #30 lake, dextrates, FD&C red #40 lake, silica gel, sorbitol, starch, stearic acid, talc, tri-calcium phosphate

package label



EXTRA STRENGTH GAS RELIEF

simethicone tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-691
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
TALC (UNII: 7SEV7J4R1U)			
TRICALCIUM PHO SPHATE (UNII: K4C08XP666)			
SORBITOL (UNII: 506T60A25R)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
DEXTRATES (UNII: G263MI44RU)			
D&C RED NO. 27 (UNII: 2LRS185U6K)			
D&C RED NO. 30 (UNII: 2S42T2808B)			

Product Characteristics					
Color	pink	Score	2 pieces		
Shape	ROUND	Size	14mm		
Flavor	CHERRY	Imprint Code	44;608		
Contains					

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:57896-691-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/0 1/20 15			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part332	11/0 1/20 15			

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Geri-Care Pharmaceuticals, Corp (611196254)

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