

EXTRA STRENGTH GAS RELIEF- simethicone capsule
KROGER COMPANY

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.

722T_Kroger_41226-722_Simethicone softgel 125mg

Drug Facts

Active ingredient

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Purpose

Anti-gas

Use

Use for the relief of

- pressure, bloating and fullness commonly referred to as gas

Warning

Warning

Keep out of reach of children.

Directions

Directions

- adults and children 12 years and older: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician

Other information

Other information

- store at room temperature

- protect from light, heat and moisture

Inactive ingredients

Inactive ingredients

D&C Yellow 10, FD&C Red #40, FD&C Blue 1, gelatin, glycerol, medium chain triglyceride, peppermint oil, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Questions or comments? Call 1-800-632-6900



EXTRA STRENGTH GAS RELIEF
simethicone capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-722

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	125 mg	
Inactive Ingredients				
Ingredient Name		Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GELATIN (UNII: 2G86QN327L)				
Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	10mm	
Flavor		Imprint Code	105	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-722-30	2 in 1 CARTON	05/05/2023	
1		15 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part332		05/05/2023	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-722)

Revised: 5/2023

KROGER COMPANY