

GAS RELIEF - simethicone tablet, chewable
McKesson Corporation dba SKY Packaging

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.

Sky Regular Strength Gas Relief Chewable Tablets

ACTIVE INGREDIENT(in each tablet)

Simethicone 80 mg

PURPOSE

Antigas

USE(S)

relieves:

- pressure
- bloating
- symptoms referred to as gas

WARNINGS

.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime
- do not exceed 6 tablets per day unless directed by a physician

OTHER INFORMATION

- do not use if inner seal is broken or missing
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

INACTIVE INGREDIENT

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol.

PRINCIPAL DISPLAY PANEL

NDC 63739-225-02

SKY

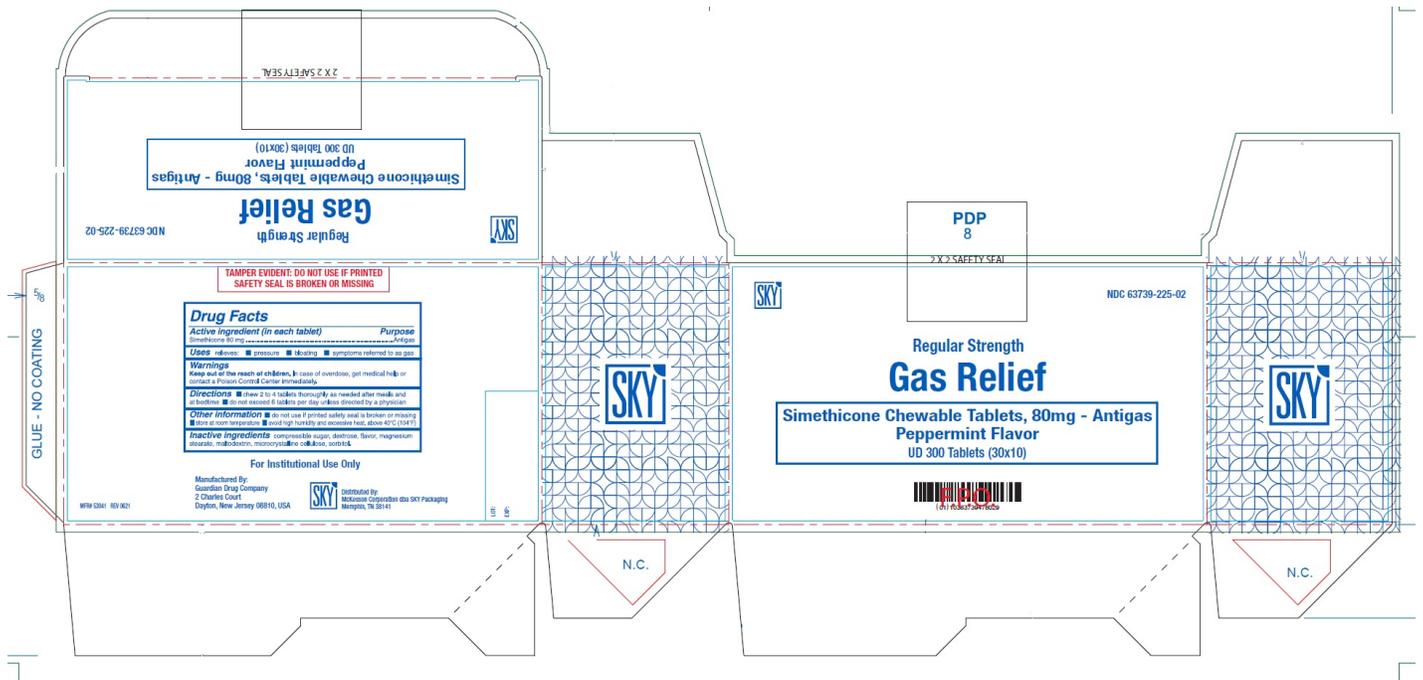
Regular Strength

Gas Relief

Simethicone Chewable Tablets, 80 mg - Antigas
Peppermint Flavor

UD 300 Tablets (30x10)

For Institutional Use Only



GAS RELIEF			
simethicone tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63739-225
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
SUGARCANE (UNII: 81H2R5AOH3)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	G103
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-225-02	30 in 1 BOX	10/19/2021	
1		10 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	10/19/2021	

Labeler - McKesson Corporation dba SKY Packaging (140529962)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(63739-225)

Revised: 4/2019

McKesson Corporation dba SKY Packaging