

**GAS RELIEF ULTRA STRENGTH- simethicone capsule, liquid filled
Preferred Pharmaceuticals Inc.**

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.

Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Antigas

Uses

- relieves bloating, pressure, or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

- swallow one or two softgels as symptoms occur
- do not exceed two softgels per 24 hours except under the advice and supervision of a physician

Other information

- store between 15-30°C (59-86°F)
- protect from heat and moisture

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin

Questions or comments?

Call **1-800-645-2158**

Principal Display Panel

Compare to the active ingredient in Phazyme® Ultra Strength†

Ultra Strength

Simethicone 180 mg

Antigas

Fast relief of

- Gas
- Pressure
- Bloating
- Discomfort

†This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of Phazyme® Ultra Strength

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by:

RUGBY® LABORATORIES

17177 N Laurel Park Drive,

Suite 233

Livonia, MI 48152

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Product Label

Simethicone Softgels 180mg

Generic for Phazyme Gas Relief
 In each softgel: Simethicone 180mg...Anti-gas
Pkg Size: Exp Date:
 Lot#: Batch#: Ins:
 Mfg: Rugby Laboratories; Livonia, MI
 Prod#:

Warning
 Stop use and ask a doctor if condition persists. Keep this and all medication out of the reach of children. If pregnant or breast-feeding, ask a health professional before use. Store at 15° - 30° C (59° - 86° F). Protect from heat and moisture. Softgel is oval, orange, imprinted with USA.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed



Simethicone Softgels 180mg
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):
 Simethicone Softgels 180mg
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):
 Simethicone Softgels 180mg
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):
 Simethicone Softgels 180mg
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):

Log
 Chart
 Billing
 Patient

RUGBY LABORATORIES Ultra Strength Simethicone

GAS RELIEF ULTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7890(NDC:0536-1306)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	05A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7890-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2021	

2	NDC:68788-7890-6	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part332		04/23/2021	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-7890)

Revised: 9/2023

Preferred Pharmaceuticals Inc.