

**GAS RELIEF ULTRA STRENGTH- simethicone 180 mg capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

SIMETHICONE 180 mg capsule, liquid filled

Active ingredient (in each capsule)

Simethicone 180 mg

Purpose

Antiflatulent

Uses for relief of:

- bloating
- pressure
- fullness
- stuffed feeling commonly referred to as gas

Warnings

Stop use and ask a doctor if condition persists.

If pregnant or breast-feeding, ask a health care 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

- swallow 1 or 2 softgels as needed after meals
- do not exceed 2 softgels per day unless directed by doctor

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- protect from heat and moisture
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, purified water, sorbitol special and white edible ink.

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

Wuhan, Hubei

430206, China

PRINCIPAL DISPLAY PANEL - Shipping Label

SIMETHICONE CAPSULES,180 mg

Quantity : 25000 Capsules

NDC. No : 53345-003-03

IMPORTANT:

Inspect immediately upon receipt.

This is a bulk shipment intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 88, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-003-03

Product:

SIMETHICONE CAPSULES,180 mg

Each softgel contains: Simethicone USP, 180 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00003

Quantity:

25000 Capsules

Lot No.:

0000000

Manufacturing Date:

00/0000

Box No.:

X

MADE IN CHINA

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.

REV - 01
01/2013

GAS RELIEF ULTRA STRENGTH

simethicone 180 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE 410 (UNII: TYU5GP6XGE) (DIMETHICONE 410 - UNII:TYU5GP6XGE)	DIMETHICONE 410	180 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE (oval)	Size	11mm
Flavor		Imprint Code	PC3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-003-03	1 in 1 BOX	04/15/2013	
1		25000 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	04/15/2013	

Labeler - Humanwell PuraCap Pharmaceutical (Wuhan), Ltd. (421293287)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-003)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.