# GAS RELIEF ULTRA STRENGTH- simethicone capsule, liquid filled LIVE BETTER (The Great Atlantic & Pacific Tea 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.

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## **Drug Facts**

### Active ingredient (in each softgel)

Simethicone 180 mg

## Purpose

Antiflatulent (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 needed after a meal
- do not exceed two softgels per day except under the advice and supervision of a physician

#### Other information

• store at 15°-30°C (59°-86°F)

#### **Inactive ingredients**

edible ink, FD&C yellow #6, gelatin, glycerin, purified water

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9 AM-5 PM EST

#### **Principal Display Panel**

\*Compare to the active ingredient in Phazyme® Ultra Strength

Ultra Strength

Gas Relief

Simethicone 180 mg

#### Antigas

- RELIEVES BLOATING AND FULLNESS
- ALSO RELIEVES PRESSURE AND GAS

#### Softgels

\*This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of Phazyme®. DISTRIBUTED BY ONPOINT, INC.

2 PARAGON DRIVE

MONTVALE, NJ 07645

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

#### **Product Label**



PLD-C FC002012

Lot No.

Simethicone 180 mg softgels

simethicone capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53187-530	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg	

Inactive Ingredients			
Ingredient Name	Strength		
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	Size	12mm	
Flavor		Imprint Code	S180	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53187-530-60	1 in 1 CARTON		
1		60 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	08/17/2010	

## Labeler - LIVE BETTER (The Great Atlantic & Pacific Tea Company) (001367366)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 4/2014 LIVE BETTER (The Great Atlantic & Pacific Tea Company)