# SANAFITIL EXTRA STRENGTH- simethicone capsule, liquid filled Promex LLC

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 Ingredients (in each softgel)

Simethicone 125mg

### 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**

• **adults:** swallow with water 1 or 2 softgels as needed after meals or at bedtime. Do not exceed 4 softgels per day, unless directed by doctor.

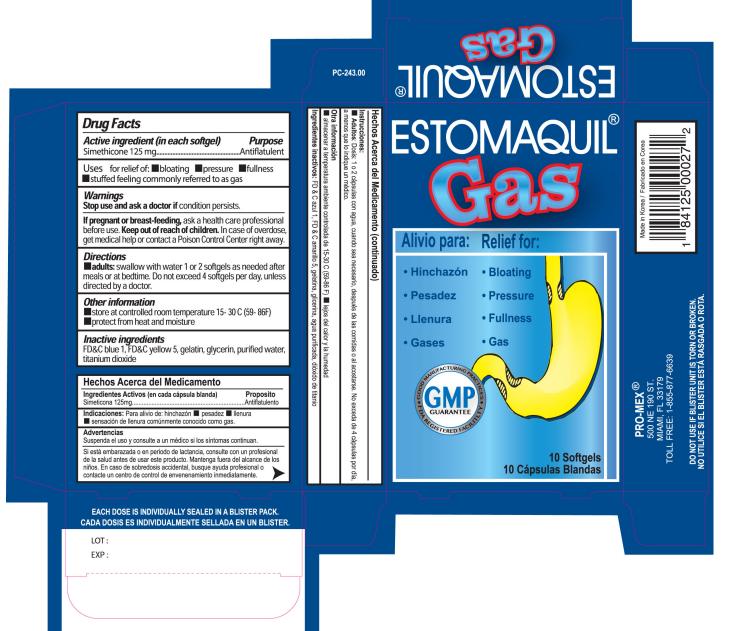
#### Other information

- store at a controlled room temperature 15-30°C (59-86°F)
- protect from heat and moisture

## **Inactive ingreients**

FD&C blue 1, FD&C yellow 5, gelatin, glycerin, purified water, titanium dioxide

#### Package/Label Principal Display Panel



### SANAFITIL EXTRA STRENGTH

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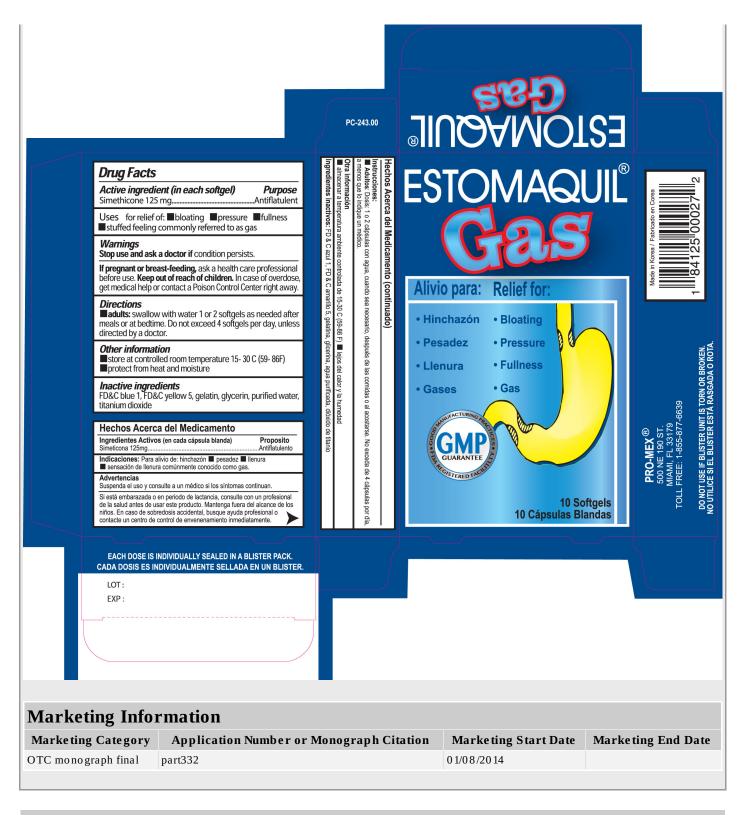
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0027
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICO NE - UNII: 92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics					
Color	green	Score	no score		
Shape	OVAL	Size	9 mm		
Flavor		Imprint Code	GR		
Contains					

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:58988-0027-1	10 in 1 BLISTER PACK				



# Labeler - Promex LLC (789974388)

Revised: 1/2015 Promex LLC