

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.

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 ingredients

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

Package/Label Principal Display Panel

PC-243.00

Drug Facts

Active ingredient (in each softgel)	Purpose
Simethicone 125mg.....	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 a doctor.

Other information
■ store at controlled room temperature 15- 30 C (59- 86F)
■ protect from heat and moisture

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

Hechos Acerca del Medicamento

Ingredientes Activos (en cada cápsula blanda)	Propósito
Simeticona 125mg.....	Antiflatulento

Indicaciones: Para alivio de: hinchazón ■ pesadez ■ llenura
■ sensación de llenura comúnmente conocido como gas.

Advertencias
Suspenda el uso y consulte a un médico si los síntomas continúan.
Si está embarazada o en periodo de lactancia, consulte con un profesional de la salud antes de usar este producto. Mantenga fuera del alcance de los niños. En caso de sobredosis accidental, busque ayuda profesional o contacte un centro de control de envenenamiento inmediatamente. ➔

ESTOMAQUIL[®]
Gas

Alivio para: Relief for:

• Hinchazón	• Bloating
• Pesadez	• Pressure
• Llenura	• Fullness
• Gases	• Gas

10 Softgels
10 Cápsulas Blandas

GMP GUARANTEE
GMP REGISTERED FACILITY

Made in Korea / Fabricado en Corea

1 84125 00027 12

Hechos Acerca del Medicamento (continuado)

Instrucciones:
■ **Adultos:** Dosis: 1 o 2 cápsulas con agua, cuando sea necesario, después de las comidas o al acostarse. No exceda de 4 cápsulas por día, o menos que lo indique un médico.

Otra información
■ almacenar a temperatura ambiente controlada de 15-30 C (59-86 F) ■ lejos del calor y la humedad

Ingredientes Inactivos: FD & C azul 1, FD & C amarillo 5, gelatina, glicerina, agua purificada, dióxido de titanio

EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK.
CADA DOSIS ES INDIVIDUALMENTE SELLADA EN UN BLISTER.

LOT :
EXP :

PRO-MEX[®]
500 NE 190 ST.
MIAMI, FL 33179
TOLL FREE: 1-855-877-6639

**DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.
NO UTILICE SI EL BLISTER ESTÁ RASGADO O ROTO.**

SANAFITIL EXTRA STRENGTH

simethicone capsule, liquid filled

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
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - 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: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	9mm
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		

PC-243.00

ESTOMAQUIL[®]
Gas

Alivio para: Relief for:

- Hinchazón
- Pesadez
- Llenura
- Gases
- Bloating
- Pressure
- Fullness
- Gas



10 Softgels
 10 Cápsulas Blandas

Made in Korea / Fabricado en Corea



PRO-MEX[®]

500 NE 190 ST
 MIAMI, FL 33179

TOLL FREE: 1-855-877-6639

DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.
 NO UTILICE SI EL BLISTER ESTÁ RASGADO O ROTO.

Drug Facts

Active ingredient (in each softgel) **Purpose**
 Simethicone 125 mg.....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 a doctor.

Other information

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

Inactive ingredients

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

Hechos Acerca del Medicamento

Ingredientes Activos (en cada cápsula blanda) **Propósito**
 Simeticona 125mg.....Antiflatulento

Indicaciones: Para alivio de: hinchazón ■ pesadez ■ llenura
 ■ sensación de llenura comúnmente conocido como gas.

Advertencias

Suspenda el uso y consulte a un médico si los síntomas continúan.

Si está embarazada o en periodo de lactancia, consulte con un profesional de la salud antes de usar este producto. Mantenga fuera del alcance de los niños. En caso de sobredosis accidental, busque ayuda profesional o contacte un centro de control de envenenamiento inmediatamente.

Hechos Acerca del Medicamento (continuado)
Instrucciones:
 ■ Adultos: Dosis: 1 o 2 cápsulas con agua, cuando sea necesario, después de las comidas o al acostarse. No exceda de 4 cápsulas por día, a menos que lo indique un médico.
Otra información
 ■ almacenar a temperatura ambiente controlada de 15-30 C (59-86 F) ■ lejos del calor y la humedad
Ingredientes Inactivos: FD & azul 1, FD & amarillo 5, gelatina, glicerina, agua purificada, dióxido de titanio

EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK.
 CADA DOSIS ES INDIVIDUALMENTE SELLADA EN UN BLISTER.

LOT :
 EXP :

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/08/2014	

Labeler - Promex LLC (789974388)

Revised: 1/2015

Promex LLC