

BLONIL - simethicone tablet, chewable
Amvilab 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 ingredient (in each tablet)

Simethicone 80 mg, USP

Purpose

Anti-Gas

Uses

Relieves bloating and pressure commonly referred to as gas.

Warnings

If pregnant or breast-feeding, ask a health professional before use.

Keep this and all drugs out of the reach of children.

Directions

- Adults: Chew 1 or 2 tablets as needed after meals and at bedtime.
- Do not exceed 6 tablets per day except under the advice and supervision of a physician.

Other Information

- Store at room temperature.
- Avoid high humidity.
- **Do not use if imprinted safety seal under cap is broken or missing.**

Inactive ingredients

Fructose, Maltodextrin, Natural and Artificial Spearmint Flavor, Silicon Dioxide, Sorbitol, Starch and Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact +1 404 256 8817.

Principal Display Panel

BLONIL

Simethicone 80 mg

Anti Gas

Relieves Gas Fast

- Pressure
- Bloating
- Discomfort

100 CHEWABLE TABLETS 80mg Each

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Simethicone 80mg, USP</td> <td>Anti-Gas</td> </tr> </tbody> </table> <p>Uses Relieves bloating and pressure commonly referred to as gas.</p> <p>Warnings If pregnant or breast-feeding, ask a health professional before use. Keep this and all drugs out of the reach of children.</p> <p>Directions Adults: Chew 1 or 2 tablets as needed after meals and at bedtime.</p>	Active ingredient (in each tablet)	Purpose	Simethicone 80mg, USP	Anti-Gas		<p>Rev. 00/00</p> <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ Do not exceed 6 tablets per day except under the advice and supervision of a physician. <p>Other information</p> <ul style="list-style-type: none"> ■ Store at room temperature. ■ Avoid high humidity. ■ Do not use if imprinted safety seal under cap is broken or missing. <p>Inactive ingredients Fructose, Maltodextrin, Natural and Artificial Spearmint Flavor, Silicon Dioxide, Sorbitol, Starch and Stearic Acid.</p> <p>Questions? If you have any questions or comments, or to report an adverse event, please contact + 1 404 256 8817</p>
Active ingredient (in each tablet)	Purpose					
Simethicone 80mg, USP	Anti-Gas					
<p>LOT# EXP. DATE:</p>	<p>Distributed By:  Atlanta, USA</p>					

BLONIL

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69975-870
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
FRUCTOSE (UNII: 6YSS42VSEV)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SORBITOL (UNII: 506T60A25R)

STARCH, CORN (UNII: O8232NY3SJ)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND (Round Flat Faced Beveled Edge)	Size	13mm
Flavor	SPEARMINT (Natural and Artificial)	Imprint Code	GPI;LB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69975-870-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/16/2015	

Labeler - Amvilab LLC (006092439)

Registrant - Gemini Pharmaceuticals, Inc. dba Plus Pharma (055942270)

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc. dba Plus Pharma		055942270	manufacture(69975-870)

Revised: 7/2015

Amvilab LLC