

**SIMETHICONE ENTERIC S.C.- simethicone tablet, sugar coated**  
**Synmosa Biopharma Corporation Synmosa Plant**

-----

**Simethicone Anti-Gas**

***Drug Facts***

***Active ingredient***

**(in each sugar-coated tablet)**

Simethicone 60 mg

***Purpose***

Anti-gas

***Use***

Relief of bloating and pressure commonly referred to as gas.

***Warnings***

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

**Keep out of reach of children.**

***Directions***

Adults and children over 12 years: one or two tablets daily, taken with meal or at bedtime.

Do not exceed 8 tablets per day except under the advice and supervision of a physician.

***Other information***

Store below 25°C (77°F).

***Inactive ingredients***

Calcium Phosphate Dibasic, Carnauba Wax, Corn Starch, FD&C Red No. 3 (Erythrosine), Gelatin, Corn Starch (Pregelatinized), Lactose Monohydrate, Hypromellose Phthalate (31% phthalate, 40 CST), Polyoxyl 40 Stearate, Polysorbate 80, Povidone K-30, Sucrose granules, Sodium Starch Glycolate, Talc, Titanium

**Questions or comments?**

[https://www.synmosa.com.tw/en/Inquiry/ugC\\_Inquiry.asp](https://www.synmosa.com.tw/en/Inquiry/ugC_Inquiry.asp)

**TAMPER EVIDENT**

Do not use if blister unit is torn, broken or shows any signs of tampering.

Simethicone Enteric S.C.

Tablets 60 mg

Composition:

Each S.C. tablet contains:

Simethicone . . . . . 60 mg

**Anti Gas**

Acts Fast to Relieve

- Gas Pressure
- Bloating
- Gas Discomfort

Manufactured by:

**Synmosa Biopharma Corporation, Synmosa Plant**

No. 6, Kuang Yeh 1 st Road, Hu-Kuo Hsiang

Hsin-Chu Ind. Park, Hsin Chu Hsien

Taiwan, R.O.C.

Made in Taiwan (R.O.C.)

synmosa

ANTI-GAS

Simethicone Enteric S.C. Tablets 60 mg


Keep outer carton for complete warnings and product information

OTC Anti-Gas Ingredient

100 Tablets

Batch No:  
Exp. Date:  
Mfg. Date:

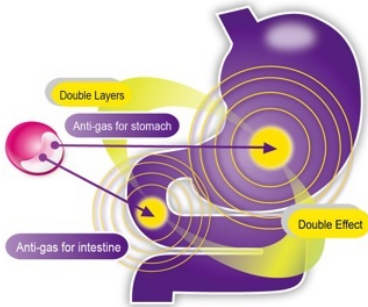
Simethicone Enteric S.C.  
Tablets 60 mg



**synmosa**

**ANTI-GAS**

Simethicone Enteric S.C. Tablets 60 mg



Keep outer carton for complete warnings and product information.

OTC Anti-Gas Ingredient

Actual Size **100** Tablets

SLB0000C

**Simethicone Enteric S.C.**  
Tablets 60 mg

**TAMPER EVIDENT**

Do not use if blister unit is torn, broken or shows any signs of tampering.

**Composition:**  
Each S.C. tablet contains:  
Simethicone.....60 mg

**Anti Gas**  
Acts Fast to Relieve

- Gas Pressure
- Bloating
- Gas Discomfort

Manufactured by:  
**Synmosa Biopharma Corporation,**  
**Synmosa Plant**  
No. 6, Kuang Yeh 1 st Road, Hu-Kuo Hsiang, Hsin-Chu Ind. Park, Hsin Chu Hsien, Taiwan, R.O.C.



4716140 000000  
Made in Taiwan (R.O.C)

**Drug Facts**

Active ingredient (in each sugar-coated tablet)	Purpose
Simethicone 60 mg.....	Anti-gas

**Use**  
Relief of bloating and pressure commonly referred to as gas.

**Warnings**  
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

**Directions**  
Adults and children over 12 years: one or two tablets daily, taken with meal or at bedtime.

Do not exceed 8 tablets per day except under the advice and supervision of a physician.

**Other information**  
Store below 25° C (77° F).

**Inactive ingredients**  
Calcium Phosphate Dibasic, Carnauba Wax, Corn Starch, FD&C Red No. 3 (Erythrosine), Gelatin, Corn Starch (Pregelatinized), Lactose Monohydrate, Hypromellose Phthalate (31% Phthalate, 40 CST), Polyoxyl 40 Stearate, Polysorbate 80, Povidone K-30, Sucrose Granules, Sodium Starch Glycolate, Talc, Titanium

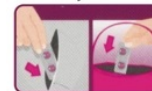
**Questions or comments?**  
[https://www.synmosa.com.tw/en/Inquiry/ugc\\_Inquiry.asp](https://www.synmosa.com.tw/en/Inquiry/ugc_Inquiry.asp)

**Simethicone Enteric S.C.**  
Tablets 60 mg

**1. Separate Blister**



**2. Carry in Purse**



**3. Press Simethicone through Foil**



**SIMETHICONE ENTERIC S.C.**

simethicone tablet, sugar coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83931-001
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	60 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)</b> (UNII: G4U024CQK6)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

<b>SUCROSE</b> (UNII: C151H8M554)
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92))
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)
<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>TITANIUM</b> (UNII: D1JT611TNE)
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)
<b>GELATIN</b> (UNII: 2G86QN327L)

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83931-001-01	10 in 1 BOX	04/01/2024	
1		10 in 1 BLISTER PACK; 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	04/01/2024	

### Labeler - Synmosa Biopharma Corporation Synmosa Plant (657895530)

### Establishment

Name	Address	ID/FEI	Business Operations
Synmosa Biopharma Corporation Synmosa Plant		657895530	manufacture(83931-001)