

ANTI-GAS STRIP - simethicone strip

Calmour

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 strip)

Simethicone 62.5 mg

Purpose

Antigas

Use

For the relief of

- Pressure
- Bloating
- Fullness commonly referred to as gas.

Warnings

- Keep out of reach of children.

Directions

- Adults and children 12 years and older: dissolve 1 or 2 oral strips on tongue when symptoms occur.
- Do not exceed more than 8 strips within 24 hours except under the advice of supervision of a medical physician.

Other Information

- Use strip immediately after opening.
- Store below 77°F (25°C). Protect from heat, light and moisture.

Inactive Ingredients

Maltodextrin, Sucralose, Polyethylene Oxide, Glycerol, Magnesium Aluminometasilicate, Hypromellose, FD & C Blue 1, Cool Mint KAL 1080.

Questions or comments?

Call 1-802-861-4111

Monday-Friday

9AM-5PM EST

Distributed by:

Calmour, LLC

1775 Williston Road

South Burlington, VT 05403

Phone (802) 861-4111

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Made in India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

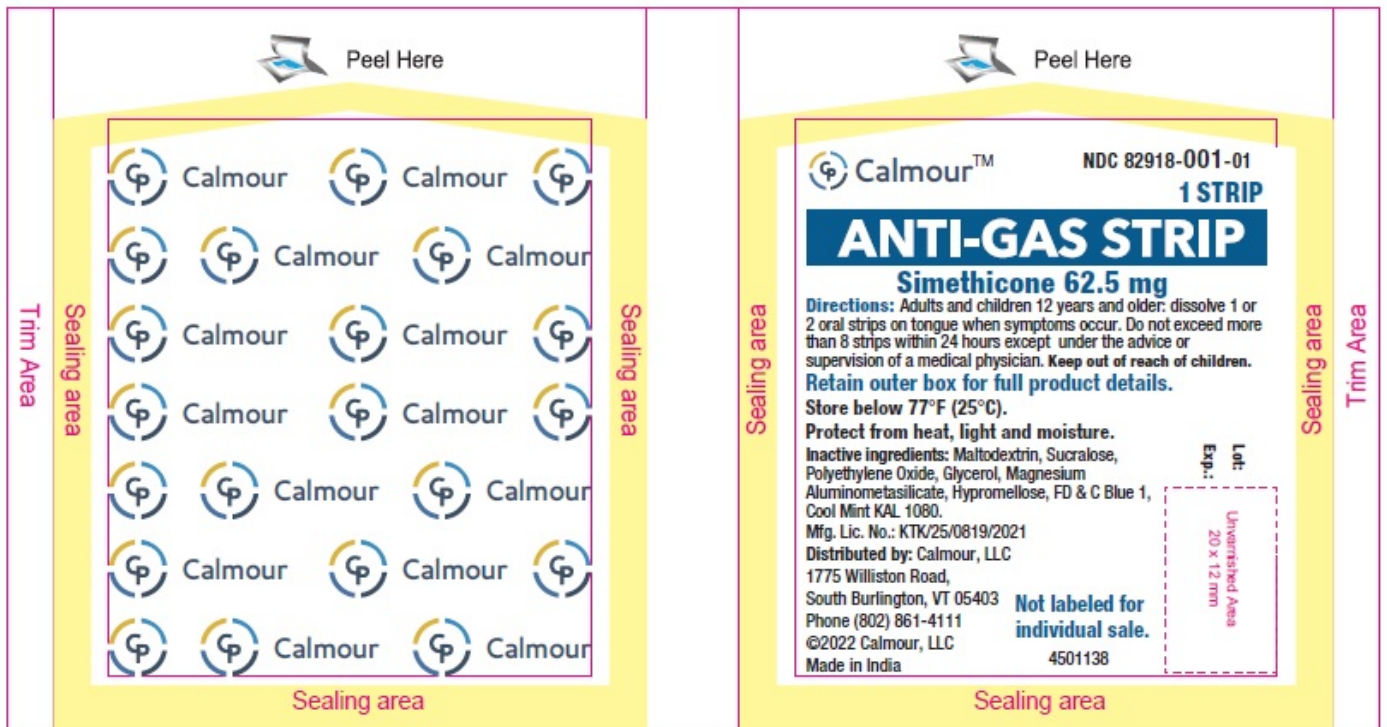
POUCH LABEL

NDC 82918-001-01

ANTI-GAS STRIP

Simethicone 62.5 mg

1 STRIP



Pouch

INNER BOX

NDC 82918-001-01

ANTI-GAS STRIPS

Simethicone 62.5 mg

Quick Dissolving Oral Strips

- Easy Peel-Open Pouches
- Pleasant Taste
- Relieves Gas

MINT FLAVOR

10 Strips

(packed individually)

(shall be printed during packing)

Lot:
Exp.:



NDC 82918-001-01

ANTI-GAS STRIPS

**SIMETHICONE
62.5 mg**

Quick-Dissolving Oral Strips

- Easy Peel-Open Pouches
- Pleasant Taste
- Relieves Gas*

10 Strips
(Packed Individually)

MINT FLAVOR

ANTI-GAS STRIPS

Unvarnished Area
70x25 mm

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Retain outer box for full product details.

4501541

Drug Facts
Active Ingredient (in each strip) Simethicone 62.5 mg
Purpose Antigas
Use for the relief of ■ Pressure, bloating and fullness commonly referred to as gas.
Warnings ■ Keep out of reach of children.
Directions ■ Adults and children 12 years and older: dissolve 1 or 2 oral strips on tongue when symptoms occur. ■ Do not exceed more than 8 strips within 24 hours except under the advice or supervision of a medical physician.
Other information ■ Use strip immediately after opening. ■ Store below 77°F (25°C). Protect from heat, light and moisture.
Inactive ingredients Aluminummetasilicate, Hypromellose, FD & C Blue 1, Cool Mint KAL 1080, Maltodextrin, Sucralose, Polyethylene Oxide, Glycerol, Magnesium



Mfg. Lot. No.: KTK/25/0819/2021
 Distributed by: Calmour, LLC
 175 Williston Road
 South Burlington, VT 05403
 Monday-Friday
 9AM-5PM EST
 Call 1-802-861-4111
 Questions or comments?
 Calmour™
 Made in India

OUTER BOX
NDC 82918-001-10
ANTI-GAS STRIPS

Simethicone 62.5 mg

Quick Dissolving Oral Strips

- Easy Peel-Open Pouches
- Pleasant Taste
- Relieves Gas

MINT FLAVOR

100 Strips

(packed individually)



30's PACK CARTON

NDC 82918-001-02

ANTI-GAS STRIPS

Simethicone 62.5 mg

Quick Dissolving Oral Strips

- Easy Peel-Open Pouches
- Pleasant Taste
- Relieves Gas

MINT FLAVOR

30 Strips

(packed individually)

(shall be printed during packing)

Lot:
Exp.:



Unvarnished Area
70x25 mm



NDC 82918-001-02

ANTI-GAS STRIPS

**SIMETHICONE
62.5 mg**

Quick-Dissolving Oral Strips

- Easy Peel-Open Pouches
- Pleasant Taste
- Relieves Gas*

30 Strips
(Packed Individually)

MINT FLAVOR

ANTI-GAS STRIPS

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This product is not intended to diagnose, treat, cure or prevent any disease.

4501573

Drug Facts

Active Ingredient (in each strip) Simethicone 62.5 mg

Purpose Antigas

Use for the relief of Pressure, bloating and fullness commonly referred to as gas.

Warnings

- Keep out of reach of children.

Directions

- Adults and children 12 years and older: dissolve 1 or 2 oral strips on tongue when symptoms occur.
- Do not exceed more than 8 strips within 24 hours except under the advice or supervision of a medical physician.

Other information

- Use strip immediately after opening.
- Store below 77°F (25°C). Protect from heat, light and moisture.

Inactive ingredients Aluminummetasilicate, Hydroxypropylmethylcellulose, Polyethylene Oxide, Magnesium Maltoedexin, Sucralose, Hypromellose, FD & C Blue 1, Cool Mint KAL 1080.



Questions or comments?
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K TK/25/0819/2021
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ANTI-GAS STRIP
simethicone strip

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82918-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	62.5 mg

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILODRATE (UNII: 9T3UU8T0QK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82918-001-10	10 in 1 CARTON	07/20/2023	
1	NDC:82918-001-01	10 in 1 CARTON		
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:82918-001-02	30 in 1 CARTON	07/20/2023	
2		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	07/20/2023	

Labeler - Calmour (118597110)

Registrant - Shilpa Medicare Limited, Unit-VI (854193706)

Establishment

Name	Address	ID/FEI	Business Operations
Shilpa Medicare Limited, Unit-VI		854193706	ANALYSIS(82918-001) , MANUFACTURE(82918-001) , PACK(82918-001) , LABEL(82918-001)

Revised: 7/2023

Calmour