

GAS RELIEF- simethicone tablet, chewable
Northeast Pharma

Heartland Pharma 44-608

Active ingredient (in each chewable tablet)

Simethicone 125 mg

Purpose

Antigas

Uses

for the relief of pressure, bloating, and fullness commonly referred to as gas

Warnings

Keep out of reach of children.

Directions

- **do not take more than directed**
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults and children 12 years and over: take 1 or 2 chewable tablets as needed after meals and at bedtime
- do not exceed 4 chewable tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- **each tablet contains:** calcium 85 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- use by expiration date on package

Inactive ingredients

crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch, sucralose, tribasic calcium phosphate

Questions or comments?

1-800-383-0648

Principal display panel

**Heartland®
Pharma Co.**

NDC 80136-859-68

Extra Strength

GAS RELIEF

Simethicone 125 mg Chewable Tablets

Antigas

**Relieves
Pressure
Bloating
Discomfort**

Compare to the
active ingredient in

Gas-X® Extra Strength*

Chew or crush tablets completely before swallowing.

100 Chewable Tablets

Actual
Size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

*This product is not manufactured or distributed by GSK Consumer
Healthcare S.A., owner of the registered trademark Gas-X® Extra Strength.
50844 ORG122060812

Distributed by:

NORTHEAST PHARMA

Williston, VT 05495

www.heartlandpharmaco.com

1-800-383-0648

NDC 80136-859-68



Extra Strength

GAS RELIEF

Simethicone 125 mg Chewable Tablets
Antigas

- Relieves
- ✓ Pressure
 - ✓ Bloating
 - ✓ Discomfort



Actual Size
Compare to the active ingredient in Gas-X® Extra Strength*

Chew or crush tablets completely before swallowing.

100 Chewable Tablets

TAMPER EVIDENT, DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts	Purpose
Active ingredient (in each chewable tablet) Simethicone 125 mg	Antigas
Uses gas	for the relief of pressure, bloating, and fullness commonly referred to as gas
Warnings	Keep out of reach of children.
Directions	<ul style="list-style-type: none"> ■ do not take more than directed ■ chew or crush tablets completely before swallowing; do not swallow tablets whole ■ adults and children 12 years and over: take 1 or 2 chewable tablets as needed after meals and at bedtime ■ do not exceed 4 chewable tablets in 24 hours unless directed by a doctor ■ children under 12 years: ask a doctor
Other information	<ul style="list-style-type: none"> ■ each tablet contains: calcium 85 mg ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ protect from moisture ■ use by expiration date on package
Inactive ingredients	crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch, sucralose, tribasic calcium phosphate
Questions or comments?	1-800-383-0648

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Heartland Pharma 44-608

GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80136-859
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
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
DIMETHICONE 410 (UNII: TYU5GP6XGE)	

Product Characteristics

Color	pink	Score	no score
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Shape	ROUND	Size	14mm
Flavor	CHERRY	Imprint Code	44;680
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-859-68	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	06/30/2023	

Labeler - Northeast Pharma (081232935)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(80136-859) , pack(80136-859)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(80136-859)

Revised: 6/2023

Northeast Pharma