

FOSTER AND THRIVE INFANTS GAS RELIEF - simethicone solution/ drops
Strategic Sourcing Services 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.

Foster and Thrive infants Gas relief 520

ACTIVE INGREDIENT(S)

Simethicone 20 mg

PURPOSE

Antigas

USE(S)

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

WARNINGS

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WHEN USING THIS PRODUCT

do not exceed 12 doses per day

KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

DIRECTIONS

- shake well before using
- all dosages may be repeated as needed, after meals and at bedtime
- fill enclosed dropper to recommended dosage level
- dispense liquid slowly into baby's mouth, toward the inner cheek
- may mix with 1 oz. of cool water, infant formula or other suitable liquids.
- clean dropper after each use and close the bottle to maintain child resistance

age (yr)	weight (lb)	dose
infants under 2	under 24	0.3 mL
children over 2	over 24	0.6 mL

OTHER INFORMATION

store at room temperature

INACTIVE INGREDIENTS

benzoic acid, flavor, magnesium aluminum silicate, purified water, simethicone emulsion, sorbitol, xanthan gum.

QUESTIONS OR COMMENTS?

Call **833-358-6431** Monday to Friday 9:00 to 7:00 pm EST

PRINCIPAL DISPLAY PANEL

NDC 70677-1078-1

COMPARE TO MYLICON[®] NON-STAINING INFANTS' DROPS

ACTIVE INGREDIENT*

Foster and Thrive[™]

INFANTS'

Gas Relief Drops

Simethicone 20 mg

ANTIGAS

Relief of gas symptoms:

- Pressure
- Bloating

- Non-staining Formula
- Alcohol Free
- Saccharin Free

1 FL. OZ. (30 mL) 100 Doses

COATING FREE AREA

SEALED WITH PRINTED NECK BAND FOR YOUR PROTECTION.

Drug Facts

Active ingredient (in each 0.3 mL) Simethicone 20 mg	Purpose Antigas
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Uses relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

Warnings
When using this product do not exceed 12 doses per day
Keep out of the reach of children. In case of overdose get medical help or contact a poison control center right away (1-800-222-1222).

Directions ■ shake well before using
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Other information store at room temperature

Inactive ingredients benzoic acid, flavor, magnesium aluminum silicate, purified water, simethicone emulsion, sorbitol, xanthan gum.

Questions or comments? Call 833-358-4431
Monday to Friday 9:00 am to 7:00 pm EST

KEEP CARTON FOR COMPLETE INFORMATION.

COATING FREE AREA

Foster & Thrive™
INFANTS'
Gas Relief Drops

COMPARE TO MYLICON®
NON-STAINING INFANTS' DROPS
ACTIVE INGREDIENT*

NDC 70677-1078-1

Foster & Thrive™
INFANTS'
Gas Relief Drops
Simethicone 20 mg
ANTIGAS

Relief of gas symptoms:

- Pressure
- Bloating
- Non-staining Formula
- Alcohol Free
- Saccharin Free

1 FL. OZ. (30 mL) 100 DOSES

MFR# 53041 REV 0423



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LOT: Blank Area for LOT & EXP. Information

EXP: Information

COATING FREE AREA

Foster & Thrive™
INFANTS'
Gas Relief Drops

*This product is not manufactured or distributed by Infirst Healthcare, Inc., the distributor of Mylicon® Infant Drops.

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Memphis, TN 38141
Money Back Guarantee
www.fosterandthrive.com

NDC 70677-1078-1

Foster & Thrive™

INFANTS'
Gas Relief
Drops

Simethicone 20 mg
ANTIGAS

1 FL. OZ. (30 mL)
100 DOSES

SEAL WITH PRINTED NECK BAND FOR YOUR PROTECTION.

Drug Facts		
Active ingredient (in each 0.3 mL) Purpose Simethicone 20 mg.....Antigas		
Uses relieves the symptoms of gas		
Warnings When using this product do not exceed 12 doses per day Keep out of the reach of children. In case of overdose get medical help or contact a poison control center right away (1-800-222-1222).		
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NPN# 63041 REV 04-23

LOT: / EXP. (UNFINISHED AREA TO BE LEFT BLANK FOR LOT & EXP. INFORMATION) (LINE DOES NOT PRINT)

KEEP CARTON FOR COMPLETE INFORMATION.

FOSTER AND THRIVE INFANTS GAS RELIEF

simethicone solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1078
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
Magnesium Aluminum silicate (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1078-1	1 in 1 CARTON	06/12/2023	
1		30 mL in 1 BOTTLE, DROPPER; 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	06/12/2023	

Labeler - Strategic Sourcing Services LLC (116956644)**Establishment**

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70677-1078)

Revised: 6/2023

Strategic Sourcing Services LLC