FOSTER AND THRIVE EXTRA STRENGTH GAS RELIEF CHERRY - simethicone tablet, chewable 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 Extra strength Gas Relief Cherry

ACTIVE INGREDIENT(in each tablet)

Simethicone 125 mg

PURPOSE

Anti-gas

USE(S)

relieves:

- pressure
- bloating
- symptoms referred to as gas

WARNINGS

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KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a poison control center immediately (1-800-222-1222).

DIRECTIONS

- chew 1 to 2 tablets thoroughly as needed after meals and at bedtime
- do not exceed 4 tablets in a 24 hour period except under the advice and supervision of a physician.

OTHER INFORMATION

- do not use if any individual blister unit is broken or open
- store at room temperature
- avoid high humidity and excessive heat, above 40°C (104°F)

INACTIVE INGREDIENTS

D&C red # 30 aluminum lake, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol, sucrose.

QUESTIONS OR COMMENTS?

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

PRINCIPAL DISPLAY PANEL

NDC 70677-1077-1

COMPARE TO GAS-X® EXTRA STRENGTH ACTIVE INGREDIENT*

Foster & Thrive TM
EXTRA STRENGTH
Gas Relief
Simethicone 125 mg
ANTIGAS

Relieves these gas symptoms:

- Discomfort
- Pressure
- Bloating

CHERRY FLAVOR

18 CHEWABLE TABLETS



FOSTER AND THRIVE EXTRA STRENGTH GAS RELIEF CHERRY

simethicone tablet, chewable

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70677-1077 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--------------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) | DIMETHICONE | 125 mg | | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| D&C RED NO. 30 (UNII: 2S42T2808B) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCROSE (UNII: C151H8M554) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) | |
| | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | PINK | Score | no score |
| Shape | ROUND | Size | 14mm |
| Flavor | CHERRY | Imprint Code | G134 |
| Contains | | | |

| F | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70677- 1077-1 | 2 in 1 CARTON | 05/25/2023 | |
| 1 | - | 9 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 FINAL | part332 | 05/25/2023 | |
| | | | |

Labeler - Strategic Sourcing Services LLC (116956644)

| Establishment | | | | |
|-----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Guardian Drug Company | | 119210276 | MANUFACTURE(70677-1077) | |

Revised: 5/2023 Strategic Sourcing Services LLC