GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled McKesson (Sunmark)

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.

Sunmark 44-664

Active ingredient (in each liquid-filled capsule)

Simethicone 125 mg

Purpose

Antigas

Use

relieves bloating, pressure, fullness, or stuffed feeling commonly referred to as gas

Warnings

Keep out of reach of children.

Directions

- adults: swallow with water 1 or 2 capsules as needed after meals and at bedtime
- do not exceed 4 capsules in 24 hours unless directed by a doctor

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from heat and moisture
- see end flap for expiration date and lot number

Inactive ingredients

D&C yellow #10, edible white ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, lecithin, mineral oil, peppermint oil, purified water, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

sunmark®

COMPARE TO GAS-X[®] EXTRA STRENGTH ACTIVE INGREDIENT* NDC 49348-073-09

Extra Strength gas relief SIMETHICONE 125 mg Antigas

relieves pressure bloating discomfort

EASY TO SWALLOW

50 SOFTGELS

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Gas-X[®] Extra Strength. 50844 ORG091466415

Product of China Packaged and Quality Assured in the USA

MCKESSON

Another Quality Product Distributed by McKesson One Post Street, San Francisco, CA 94104 Money Back Guarantee Please visit us at www.sunmarkbrand.com



Sunmark 44-664

| GAS RELIEF EXTRA ST | FRENGTH | | | | | |
|---|----------------|--------------------|--|---------------|----------|--|
| simethicone capsule, liquid filled | | | | | | |
| | | | | | | |
| Product Information | | | | | | |
| Product T ype | HUMAN OTC DRUG | Item Code (Source) | | NDC:49348-073 | | |
| Route of Administration | ORAL | | | | | |
| | | | | | | |
| | | | | | | |
| Active Ingredient/Active Moi | e ty | | | | | |
| Ingredient Name Basis of S | | | | | Strength | |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETH | | | | Е | 125 mg | |
| | | | | | | |
| | | | | | | |
| Inactive Ingredients | | | | | | |
| Ingredient Name | | | | | Strength | |
| D&C YELLOW NO. 10 (UNII: 35SW5U | SQ3G) | | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBI |)) | | | | | |

| FD&C RED NO. 40 (U | | | | | | |
|-----------------------------|---|------------------------|--------------------|----------------------|----------------------|--|
| GELATIN (UNII: 2G86 | 5QN327L) | | | | | |
| GLYCERIN (UNII: PD | C6A3C0O | X) | | | | |
| MINERAL OIL (UNII: | T5L8T28 | FGP) | | | | |
| PEPPERMINT OIL (U | INII: AV09 | 2KU4JH) | | | | |
| WATER (UNII: 059QF | 0KO0R) | | | | | |
| TITANIUM DIO XIDE | (UNII: 15F | FIX9V2JP) | | | | |
| LECITHIN, SOYBEA | N (UNII: 1I | DI56QDM62) | | | | |
| | | | | | | |
| | | | | | | |
| Product Charact | eristics | | | | | |
| Color | | GREEN | Score | | no score | |
| Shape OVAL | | OVAL | Size | | 9 m m | |
| Flavor | | | Imprint Code | | 664 | |
| Contains | | | | | | |
| | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | | Package Description | | Marketing Start Dat | e Marketing End Date | |
| 1 NDC:49348-073- 09 | 5 in 1 CARTON | | 0 3/0 1/20 15 | | | |
| 1 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | | | | |
| | | | | | | |
| | | | | | | |
| Marketing Information | | | | | | |
| Marketing Catego | ory A | pplication Number or 1 | Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH FINAL part332 | | | 03/01/2015 | | | |
| OIC MONOGRAFIIFI | INAL par | 1332 | | 0 5/0 1/20 15 | | |

Labeler - McKesson (Sunmark) (177667227)

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------|
| LNK International, Inc. | | 967626305 | PACK(49348-073) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | PACK(49348-073) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| | | 868734088 | PACK(49348-073) |

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|----------------------------|
| LNK International, Inc. | | 038154464 | PACK(49348-073) |

Revised: 6/2019