MI-ACID GAS RELIEF- simethicone tablet, chewable NuCare Pharmaceuticals, Inc.

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.

Mi-Acid Gas Relief

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Antigas

Uses

relieves:

- pressure
- bloating
- symptoms referred to as gas

Warnings

Keep out of the reach of children. In case of overdose, get medical help or contact a poison control center immediately.

Directions

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime.
- do not exceed 6 tablets per day unless directed by a physician.

Other information

- do not use if inner seal is broken.
- store at room temperature
- avoid high humidity and excessive heat, above 40 0 C (104 0 F)

Inactive ingredients

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol

Questions or comments?

PDP



MI-ACID GAS RELIEF

simethicone tablet, chewable

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68071-5136(NDC:0904-5068)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)

DIMETHICONE

80 mg

Inactive Ingredients

Ingredient Name

SUCROSE (UNII: C151H8M554)

DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

SORBITOL (UNII: 506T60A25R)

Product Characteristics

| 1 Todact Characteristics | | | | |
|--------------------------|-------|-------|----------|--|
| Color | white | Score | no score | |
| Shape | ROUND | Size | 13mm | |

| Packaging | | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:68071- 5136-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 12/17/2019 | | |
| | | | | | |

Imprint Code

GDC103

| Marketing Information | | | | | | |
|-----------------------|---|-------------------------|-----------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph final | part332 | 03/02/2011 | | | | |
| | | | | | | |

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

PEPPERMINT

Flavor

Contains

| Establishment | | | | | | |
|------------------------------|---------|-----------|----------------------------|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| NuCare Pharmaceuticals, Inc. | | 010632300 | repack(68071-5136) | | | |

Revised: 2/2021 NuCare Pharmaceuticals,Inc.