GAVISCON- aluminum hydroxide and magnesium carbonate liquid Haleon US Holdings LLC

Drug Facts

Active ingredients (in each 15 mL tablespoonful) Regular Strength

Aluminum hydroxide 95 mg

Magnesium carbonate 358 mg

Active ingredients (in each 5 mL teaspoonful) Extra Strength

Aluminum hydroxide 254 mg Magnesium carbonate 237.5 mg

Purpose

Antacid

Uses

relieves

- heartburn
- acid indigestion
- sour stomach
- upset stomach associated with these symptoms

Warnings

Ask a doctor or pharmacist before use if you

- have kidney disease.
- are on a sodium-restricted diet or a magnesium-restricted diet.
- are taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product (Regular Strength)

- do not take more than 8 tablespoonfuls in 24 hours
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor
- laxative effect may occur

When using this product (Extra Strength)

- do not take more than 16 teaspoonfuls in 24 hours
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor

laxative effect may occur

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions (Regular Strength)

- shake well
- take 1-2 tablespoonfuls four times a day or as directed by a doctor
- take after meals and at bedtime
- dispense product only by spoon or other measuring device

Directions (Extra Strength)

- shake well
- take 2-4 teaspoonfuls four times a day or as directed by a doctor
- take after meals and at bedtime
- dispense product only by spoon or other measuring device

Other information (Regular Strength)

- each tablespoon (15 mL) contains: magnesium 115 mg, sodium 52 mg
- store at up to 25°C (77°F). Avoid freezing.
- keep tightly closed

Other information (Extra Strength)

- each teaspoon (5 mL) contains: magnesium 80 mg, sodium 14 mg
- store at up to 25°C (77°F). Avoid freezing.
- keep tightly closed

Inactive ingredients (Regular Strength)

benzyl alcohol, D&C yellow #10, edetate disodium, FD&C blue #1, flavor, glycerin, saccharin sodium, sodium alginate, sorbitol solution, water, xanthan gum

Inactive ingredients (Extra Strength Cool Mint)

benzyl alcohol, edetate disodium, flavor, glycerin, saccharin sodium, simethicone emulsion, sodium alginate, sorbitol solution, water, xanthan gum

Inactive Ingredients (Extra Strength Cherry)

Benzyl alcohol, edetate disodium, flavor, glycerin, saccharin sodium, simethicone emulsion, sodium alginate, sorbitol solution, water, xanthan gum

Questions or comments?

1-888-367-6471

Additional Information

Do not use if printed inner safety seal under cap is broken or missing.

Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

Made in Mexico

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Principal Display Panel

NDC 0135-0094-41

Gaviscon

LIQUID ANTACID

REGULAR STRENGTH

- Fast-Acting <u>Heartburn Relief</u>
- Helps Keep Acid Down for Hours

COOL MINT

FLAVOR

12 FL OZ (355 mL) FRONT: 00067473 BACK: 00067474



Principal Display Panel

NDC 0135-0095-41

Gaviscon

LIQUID ANTACID

EXTRA STRENGTH

- Fast-Acting <u>Heartburn Relief</u>
- Helps Keep Acid Down for Hours

COOL MINT

FLAVOR

12 FL OZ (355 mL) FRONT: 00067475 BACK: 00067476



Principal Display Panel

NDC 0135-0574-01

Gaviscon ®

EXTRA STRENGTH

LIQUID ANTACID

- Fast-Acting <u>Heartburn Relief</u>
- Helps Keep Acid Down for Hours

CHERRY

FLAVOR

12fl oz (355 ml) ©2014 GlaxoSmithKline

FRONT: 103698XA

BACK: 103699XA



GAVISCON

aluminum hydroxide and magnesium carbonate liquid

| Product Information | | | | | |
|---|--------------------------|---------------|------------------------|-------------------|------|
| Product Type | HUMAN OTC DRUG | Item Code (So | ource) | NDC:0135-009 | 4 |
| Route of Administration | ORAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active | e Molety | | | | |
| Ingi | edient Name | | Basis of Strengtl | Strop | ngth |
| ALUMINUM HYDROXIDE (UNII: 5 UNII:5QB0T2IUN0) | QB0T2IUN0) (ALUMINUM HYD | ROXIDE - | ALUMINUM HYDROXIDE | 95 mg in 15 m | L |
| MAGNESIUM CARBONATE (UNII UNII:7UJQ50PE7D) | 0E53J927NA) (CARBONATE I | ON - | MAGNESIUM CARBONATE | 358 mg in 15 m | L |
| | | | | | |
| | | | | | |

Ingredient Name

Strength

| - | - |
|--------------------------------------|---|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM ALGINATE (UNII: C269C4G2ZQ) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| Color | green | Score |
|----------|------------------|--------------|
| Shape | | Size |
| Flavor | MINT (cool mint) | Imprint Code |
| Contains | | |

Packaging

| # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|---|-------------------------|-----------------------|
| | NDC:0135-0094- 41 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/14/2011 | |
| | | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/14/2011 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|--------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC Monograph Drug | M001 | 01/14/2011 | |

GAVISCON

aluminum hydroxide and magnesium carbonate liquid

| Product Information | | | | | | |
|-------------------------|----------------|--------------------|---------------|--|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0095 | | | |
| Route of Administration | ORAL | | | | | |

| Active Ingredient/Active Moiety | | | | | |
|---|-----------------------|-------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) | ALUMINUM HYDROXIDE | 254 mg in 5 mL | | | |
| MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - | MAGNESIUM | 237.5 mg | | | |

| Inactive Ingree | dients | | |
|-----------------------|---|-------------------------|-----------------------|
| | Ingredient Name | | Strength |
| BENZYL ALCOHOL | (UNII: LKG8494WBH) | | |
| EDETATE DISODIU | M (UNII: 7FLD91C86K) | | |
| GLYCERIN (UNII: PDO | C6A3C0OX) | | |
| SACCHARIN SODIU | M (UNII: SB8ZUX40TY) | | |
| DIMETHICONE (UNI | I: 92RU3N3Y1O) | | |
| SILICON DIOXIDE (| UNII: ETJ7Z6XBU4) | | |
| SODIUM ALGINATE | (UNII: C269C4G2ZQ) | | |
| SORBITOL (UNII: 50 | 6T60A25R) | | |
| WATER (UNII: 059QF | OKOOR) | | |
| XANTHAN GUM (UN | II: TTV12P4NEE) | | |
| | | | |
| | | | |
| Product Chara | cteristics | | |
| Color | green | Score | |
| Shape | | Size | |
| Flavor | MINT (cool mint) | Imprint Code | |
| Contains | | | |
| | | | |
| | | | |
| Packaging | | | |
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/14/2011 | |
| | | | |
| Marketing I | nformation | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| Category | Citation | Date | Date |

GAVISCON

aluminum hydroxide and magnesium carbonate liquid

| Product Information | | | | | |
|---------------------------------|----------------|----------------|----------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Sou | irce) | NDC:0135-0574 | |
| Route of Administration | ORAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingro | diant Nama | | Basis of | Strongth | |

| путеант мате | Strength | Strength |
|---|-----------|----------|
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - | ALUMINUM | 254 mg |
| UNII:5QB0T2IUN0) | HYDROXIDE | in 5 mL |
| MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - | MAGNESIUM | 237.5 mg |
| UNII:7UJQ5OPE7D) | CARBONATE | in 5 mL |

| Inactive Ingredients | | | | |
|---|----------------------------------|-----------|-------------------------|-----------------------|
| | Ingredient Name | | | Strength |
| BENZYL ALCOHOL (UNII: LKG84 | 194WBH) | | | |
| EDETATE DISODIUM (UNII: 7FL | D91C86K) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SACCHARIN SODIUM (UNII: SB | BZUX40TY) | | | |
| DIMETHICONE (UNII: 92RU3N3Y | 10) | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6 | XBU4) | | | |
| SODIUM ALGINATE (UNII: C269 | C4G2ZQ) | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| XANTHAN GUM (UNII: TTV12P4N | IEE) | | | |
| | | | | |
| | | | | |
| Product Characteristic | s | | | |
| Color | white | Score | | |
| Shape | | Size | | |
| Flavor | CHERRY | Imprint C | Code | |
| Contains | | | | |
| | | | | |
| | | | | |
| Packaging | | | | |
| # Item Code | Package Description | | Marketing Start Date | Marketing End Date |
| 1 NDC:0135-0574- 355 mL in 1 01 Product | BOTTLE; Type 0: Not a Con | mbination | 08/01/2014 | |
| | | | | |
| Marketing Informa | ation | | | |
| Marketing Applic Category | cation Number or Mon Citation | ograph | Marketing Start Date | Marketing End Date |

| Category | Citation | Date | Dat |
|--------------------|----------|------------|-----|
| OTC Monograph Drug | M001 | 08/01/2014 | |
| | | | |

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024

Haleon US Holdings LLC