

HALLS MENTHO-LYPTUS- menthol lozenge
Mondelez Global 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.

Halls mentholiptus bag

Active Ingredient

<(per drop) Menthol 5.4 mg>

Purposes

<Cough Suppressant, Oral Anesthetic>

Uses

<temporarily relieves:>

- cough due to a cold
- occasional minor irritation or sore throat

Warnings

< **Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, swelling, or vomiting, consult a doctor promptly. These may be serious.>

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens

Keep out of reach of children

Enter section text here

Directions

- adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

- 10 calories per drop
- **Contains: SOY.**

Inactive ingredients

<citric acid, eucalyptus oil, FDC blue 1, FDC red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucrose, water>

Questions

<Call **1-800-524-2854**, Monday to Friday, 9AM-6PM Eastern Time or **visit our website at** www.gethalls.com>

OTC Principal Display Panel



| HALLS MENTHO-LYPTUS | | | |
|--|--|---------------------------|-----------------|
| menthol lozenge | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12546-112 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5.4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| SUCROSE (UNII: C151H8M554) | |
| CORN SYRUP (UNII: 9G5L16BK6N) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|-----------------------------------|---------------------|----------|
| Color | blue (LIGHT BLUE WTH BLUE SPECKS) | Score | no score |
| Shape | OVAL | Size | 21mm |
| Flavor | MENTHOL (MENTHO-LYPTUS) | Imprint Code | H |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:12546-112-30 | 30 in 1 BAG; Type 0: Not a Combination Product | 04/07/2019 | |
| 2 | NDC:12546-112-14 | 14 in 1 BAG; Type 0: Not a Combination Product | 09/01/2020 | 03/21/2023 |
| 3 | NDC:12546-112-40 | 40 in 1 BAG; Type 0: Not a Combination Product | 04/07/2019 | 08/21/2023 |
| 4 | NDC:12546-112-80 | 80 in 1 BAG; Type 0: Not a Combination Product | 04/07/2019 | |
| 5 | NDC:12546-112-89 | 200 in 1 BAG; Type 0: Not a Combination Product | 04/07/2019 | |
| 6 | NDC:12546-112-96 | 96 in 1 BAG; Type 0: Not a Combination Product | 04/07/2019 | 04/21/2020 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 04/07/2019 | |

Labeler - Mondelez Global LLC (050964956)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Mondelez Canada Inc. | | 246791201 | manufacture(12546-112) |

