

HALLS HONEY- menthol lozenge
Mondelez Global LLC

HALLS Honey Bag

Active Ingredient

<(per drop) Menthol 1.8 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 or followed by fever, headache, rash, swelling, nausea, 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.

Directions

- <adults and children 5 years and over: dissolve 3 drops (one at a time) 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

<FD&C blue 1, FD&C red 40, FD&C yellow 5 (tartrazine), flavors, glucose syrup, honey, soy lecithin, sucrose, water>

Questions?

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

OTC Principal Display Panel



HALLS HONEY

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12546-241 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 1.8 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
| | |

| | |
|---|--|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| HONEY (UNII: Y9H1V576FH) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| SUCROSE (UNII: C151H8M554) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|----------|
| Color | yellow (Pale Yellow) | Score | no score |
| Shape | OVAL | Size | 21mm |
| Flavor | HONEY | Imprint Code | H |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:12546-241-30 | 30 in 1 BAG; Type 0: Not a Combination Product | 01/25/2019 | 06/21/2024 |
| 2 | NDC:12546-241-40 | 40 in 1 BAG; Type 0: Not a Combination Product | 01/25/2019 | 08/21/2023 |
| 3 | NDC:12546-241-80 | 80 in 1 BAG; Type 0: Not a Combination Product | 01/25/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 01/25/2019 | |

Labeler - Mondelez Global LLC (091849786)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Mondelez Canada Inc. | | 246791201 | manufacture(12546-241) |

Revised: 6/2024

Mondelez Global LLC