

HALLS KIDS HONEY APPLE- 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.

Drug Facts

Active Ingredient

<(per pop) Menthol 5 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

Directions

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

Other information

- 25 calories per pop

Inactive ingredients

<flavors, glucose syrup, honey, 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

<NDC 12546-350-10 Halls Kids Honey Apple Bag 10 ct>



HALLS KIDS

SORE THROAT & COUGH

- Effective relief for coughs and sore throats
- Pleasant cooling flavor
- A kid-friendly flavor your child will enjoy



Try flavors: Cherry & Strawberry

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| <p>Drug Facts</p> <p>Active Ingredient (per pop) Menthol 5 mg</p> <p>Purposes Cough suppressant, Oral anesthetic</p> <p>Uses temporarily relieve: in cough due to a cold in occasional minor irritation or sore throat</p> <p>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: in persistent or chronic cough such as occurs with smoking, asthma, or emphysema in cough accompanied by excessive phlegm (mucus) Stop use and ask a doctor if: in 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. in sore throat does not improve in 7 days in irritation, pain, or redness persists or worsens Keep out of reach of children.</p> | <p>Directions In adults and children 5 years and over: dissolve 1 pop slowly in the mouth. Repeat every 2 hours as needed. In children under 5 years: ask a doctor.</p> <p>Other information = 25 calories per pop</p> <p>Inactive ingredients Flavors, glucose syrup, honey, sucrose, water</p> <p>Questions? Call 1-800-824-2884, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at www.gethall.com</p> |
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DKSTR BU TE DB YMO ND EIZ GLO BAL LLC
EAS THAN OVER, NJ 07996 USA
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040 500 50 35 15 56
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CHOKING WARNING:
No for children under 4.
www.MDLZKidsSafe.com



HALLS KIDS HONEY APPLE

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12546-350 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------|----------|
| SUCROSE (UNII: C151H8M554) | |
| HONEY (UNII: Y9H1V576FH) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|----------|----------------------|--------------|----------|
| Color | yellow (pale yellow) | Score | no score |
| Shape | ROUND | Size | 20mm |
| Flavor | HONEY (Honey Apple) | Imprint Code | H |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:12546-350-10 | 10 in 1 BAG; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:12546-350-11 | 10 in 1 CARTON; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:12546-350-01 | 800 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 03/30/2020 | 05/25/2021 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part341 | 03/30/2020 | |

Labeler - Mondelez Global LLC (050964956)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-------------|--|-----------|------------------------|
| BestCo Inc. | | 002149136 | manufacture(12546-350) |
|-------------|--|-----------|------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|---------------------|
| Consumer Packaging Group Inc | | 612465950 | repack(12546-350) |

Revised: 3/2020

Mondelez Global LLC