

HALLS SUGAR FREE HONEY LEMON- 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 Minis sugar free honey lemon 24ct

Active ingredient

<(per drop) Menthol 2.5 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, persist 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.

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

Directions

- adults and children 5 years and over: dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor

Other information

- excessive consumption may have a laxative effect
- <5 calories per drop
- **Contains: SOY.**

Inactive ingredients

<beta carotene, citric acid, eucalyptus oil, flavors, isomalt, soy lecithin, sucralose, water>

Questions

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

OTC Principal Display Panel





PULL DOWN



HALLS,
MINIS
SUGAR FREE

HONEY LEMON FLAVOR

Drug Facts

Active ingredient (per drop) Menthol 2.5 mg 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.
■ **Use a deicer before use if you have:**
■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema
■ cough accompanied by excessive phlegm (mucus)

Stay use and eat a deicer 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 throat does not improve in 7 days
■ irritation, pain, or redness persists or worsens
■ keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Directions

■ adults and children 5 years and over: dissolve 2 drops (one at a time) slowly in the mouth. Repeat every 2 hours as needed
■ children under 5 years: ask a doctor

Other information

■ excessive consumption may have a laxative effect
■ 55 calories per drop
■ Contains 50%
■ Contains Menthol, sucrose, water, sorbitol, soy lecithin, sucralose, xanthan

Inactive ingredients: beta carotene, citric acid, eucalyptus oil, flavor, sorbitol, soy lecithin, sucralose, water

Questions?

Call 1-800-504-2854, Monday to Friday, 9 AM - 6 PM Eastern Time or visit our website at www.gskhalls.com

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EAST RUTHERFORD, NJ 07073 USA
MONDELÉZ

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CHOKING WARNING:
Not for children under 4.
www.MiDZsafety.com



HALLS SUGAR FREE HONEY LEMON

menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12546-347 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 2.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| .BETA.-CAROTENE (UNII: 01YAE03M7J) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| ISOMALT (UNII: S870P55O2W) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| SUCRALOSE (UNII: 96K6UQ3Z D4) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|--------------|--------|--------------|----------|
| Color | yellow | Score | no score |
|--------------|--------|--------------|----------|

| Shape | ROUND | Size | 9mm | |
|------------------------------|--|---|----------------------|--------------------|
| Flavor | HONEY (Honey Lemon) | Imprint Code | H | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:12546-347-03 | 11667 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 10/21/2020 | 10/03/2022 |
| 2 | NDC:12546-347-24 | 24 in 1 PACKAGE; Type 0: Not a Combination Product | 10/21/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part341 | 10/21/2020 | | |

Labeler - Mondelez Global LLC (050964956)

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| MSI Express Inc | | 117942991 | pack(12546-347) |

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Mondelez Canada Inc | | 246791201 | manufacture(12546-347) |

Revised: 10/2022

Mondelez Global LLC