

**LUDENS ORIGINAL MENTHOL THROAT DROPS- menthol lozenge**

**LUDENS HONEY LICORICE THROAT DROPS- menthol lozenge**

**LUDENS HONEY LEMON THROAT DROPS- menthol lozenge**

**Prestige Brands Holdings, Inc.**

*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.*

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## **Ludens Menthol Throat Lozenges**

### **Luden's Original Menthol Throat Drops**

#### ***Drug Facts***

#### ***Active ingredient (in each drop)***

Menthol 2.5 mg

#### ***Purpose***

Oral anesthetic

#### ***Uses***

- temporarily relieves: occasional minor irritation, pain, sore mouth, and 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.

#### **Stop use and ask a doctor if:**

- sore mouth does not improve in 7 days
- irritation, pain or redness lasts or worsens.

#### **If pregnant or breast-feeding,**

ask a doctor before use.

#### **Keep out of reach of children**

#### ***Directions***

- **adults and children 3 years of age and older:** allow drop to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by doctor.
- **children under 3 years of age:** ask a doctor

#### ***Other information***

- store at 20-25°C (68-77°F) in a dry place
- Do not use if clear outer wrap is opened or missing.

### ***Inactive ingredients***

Caramel Color, Corn Syrup, Flavors, Sodium Acetate, Soybean Oil used as a processing aid, Sucrose, Water

### ***Questions or comments?***

Call 1-866-583-3677

## **Luden's Honey Licorice Throat Drops**

### ***Drug Facts***

#### ***Active ingredient (in each drop)***

Menthol 1.0 mg

#### ***Purpose***

Oral anesthetic

#### ***Uses***

- temporarily relieves: occasional minor irritation, pain, sore mouth, and 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.

#### **Stop use and ask a doctor if**

- sore mouth does not improve in 7 days
- irritation, pain or redness lasts or worsens

#### **If pregnant or breast-feeding,**

ask a doctor before use.

#### **Keep out of reach of children**

#### ***Directions***

- **adults and children 3 years of age and older:** allow 2 drops to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.
- **children under 3 years of age:** ask a doctor

#### ***Other information***

- store at 20-25°C (68-77°F) in a dry place
- do not use if clear outer wrap is opened or missing.

### ***Inactive ingredients***

Caramel Color, Corn Syrup, Flavors, Glycerin, Honey, Sodium Acetate, Soybean Oil used as a processing aid, Sucrose, Water

## ***Questions or comments?***

call 1-866-583-3677

## **Luden's Honey Licorice Throat Drops**

### ***Drug Facts***

#### ***Active ingredient (in each drop)***

Menthol 1.6 mg

#### ***Purpose***

Oral anesthetic

#### ***Uses***

- for temporary relief of occasional minor irritation, pain, sore mouth, and 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.

#### **Stop use and ask a doctor if**

- sore mouth does not improve in 7 days
- irritation, pain or redness persists or worsens.

#### **If pregnant or breast-feeding,**

ask a health professional before use.

#### **Keep out of reach of children**

#### ***Directions***

- **Adults and children 3 years of age and older:**
- allow 1 drop at a time to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.
- **Children under 3 years of age:** ask a doctor

#### ***Other information***

- store at 20-25°C (68-77°F) in a dry place

#### ***Inactive ingredients***

caramel color, corn syrup, flavors, glycerin, honey, sodium acetate, soybean oil, sucrose.

## ***Questions?***

1-866-583-3677 Ludens.com

## **Luden's Honey Lemon Throat Drops**

### ***Drug Facts***

#### ***Active ingredient (in each drop)***

Menthol 1.0 mg

#### ***Purpose***

Oral anesthetic

#### ***Uses***

- temporarily relieves: occasional minor irritation, pain, sore mouth, and 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.

#### **Stop use and ask a doctor if**

- sore mouth does not improve in 7 days
- irritation, pain or redness lasts or worsens

#### **If pregnant or breast-feeding,**

ask a doctor before use.

#### **Keep out of reach of children**

#### ***Directions***

- **adults and children 3 years of age and older:** allow 2 drops to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.
- **children under 3 years of age:** ask a doctor

#### ***Other information***

- store at 20-25°C (68-77°F) in a dry place
- do not use if clear outer wrap is opened or missing.
- contains FD&C yellow no. 5 (tartrazine) as a color additive

#### ***Inactive ingredients***

ascorbic acid, citric acid, corn syrup, FD&C yellow 5, flavors, honey, sodium acetate, sodium chloride, soybean oil, sucrose

#### ***Questions?***

**1-866-583-3677 Ludens.com**

## **Luden's Honey Lemon Throat Drops**

### ***Drug Facts***

### ***Active ingredient (in each drop)***

Menthol 1.6 mg

### ***Purpose***

Oral anesthetic

### ***Uses***

- for temporary relief of occasional minor irritation, pain, sore mouth, and 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.

### **Stop use and ask a doctor if**

- sore mouth does not improve in 7 days
- irritation, pain or redness persists or worsens.

### **If pregnant or breast-feeding,**

ask a health professional before use.

### **Keep out of reach of children**

### ***Directions***

- **Adults and children 3 years of age and older:** 2 drops.
- allow 1 drop at a time to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.
- **Children under 3 years of age:** ask a doctor

### ***Other information***

- store at 20-25°C (68-77°F) in a dry place
- contains FD&C yellow no. 5 (tartrazine) as a color additive

### ***Inactive ingredients***

caramel color, corn syrup, flavors, glycerin, honey, sodium acetate, soybean oil, sucrose.

### ***Questions?***

1-866-583-3677 [Ludens.com](http://Ludens.com)

## **PRINCIPAL DISPLAY PANEL**

**LUDEN'S  
ORIGINAL MENTHOL  
Menthol lozenge  
Oral Anesthetic**

14 Drops



**Principal Display Panel**

**LUDEN'S**  
**HONEY LICORICE**  
**Menthol lozenge/Oral Anesthetic**  
**20 Drops**



**Principal Display Panel**

**LUDEN'S  
 HONEY LICORICE  
 Menthol lozenge  
 Oral Anesthetic  
 30 Drops**

← tear here • resealable bag



Uniquely GOOD! LUDEN'S®



HONEY LICORICE

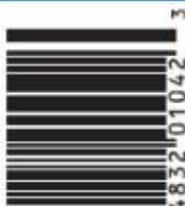
GREAT TASTING THROAT DROPS
Soothes Everyday Throat Irritation
Menthol Lozenge/Oral Anesthetic



©D

30 Drops

Save the warm hug! These throat soothers soothe for more than 2 days, to accompany or followed by fever, headache, rash, swelling, nausea or vomiting, consult your doctor for more help. These may be set later. Stop use and ask a doctor if your throat does not improve in 7 days. If irritation, pain or redness persists or worsens. If pregnant or nursing, use a throat lozenge. Professional advice is recommended. Keep out of reach of children.
Directions: Adults and children 5 years of age and older: 2 drops, allow 1 drop at a time to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.
Children under 5 years of age: as directed by a doctor.
Other information:
• Store a 100 mg (2.0 x 2.0 cm) in a dry place.
Inactive ingredients: carmelum, cornstarch, dextrose, glycerin, honey, polyethylene glycol, soybean oil, sucrose.
Questions? 1-800-583-3077 ludens.com





### Principal Display Panel

**LUDEN'S**  
**HONEY LEMON**  
**Menthol lozenge**  
**Oral Anesthetic**  
**14 Drops**



**Principal Display Panel**

**LUDEN'S  
HONEY LEMON  
Menthol lozenge  
Oral Anesthetic  
30 Drops**

**Drug Facts**

Active ingredient (in each drop)	Purpose
Menthol 10 mg	Oral anesthetic

**Uses** ■ temporarily relieves: occasional minor irritation, pain, sore mouth, and 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.

**Stop use and ask a doctor if:** ■ sore mouth does not improve in 7 days ■ irritation, pain or redness lasts or worsens.

**If pregnant or breast-feeding,** ask a doctor before use.

**Keep out of reach of children**

**Directions** ■ **adults and children 3 years of age and older:** allow 2 drops to dissolve slowly in mouth. Repeat as necessary every 2 hours, or as directed by a doctor.  
■ **children under 3 years of age:** ask a doctor

**Other information** ■ store at 20-25°C (68-77°F) in a dry place ■ do not use if clear outer wrap is opened or missing. ■ contains FD&C yellow no. 5 (tartrazine) as a color additive.

**Inactive ingredients** Ascorbic Acid, Citric Acid, Corn Syrup, FD&C Yellow No. 5, Flavors, Honey, Sodium Acetate, Sodium Chloride, Soybean Oil used as a processing aid, Sucrose, Water

**Questions or comments?** Call 1-866-583-3677

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The advertisement features a vibrant yellow background with several whole lemons and orange slices scattered throughout. The text is arranged in a clean, modern layout. At the top right, a green slogan reads 'Soothes Your Throat Tastes Great!'. A large, white, tilted banner in the center contains the brand name 'LUDEN'S.' in bold black letters with a green outline. Below this banner, the text 'Menthol Lozenge/Oral Anesthetic' is written in a smaller, italicized green font. The flavor 'Honey Lemon' is prominently displayed in a large, bold, green font. At the bottom right, the quantity '30 Throat Drops' is written in a bold green font.

**Soothes Your Throat  
Tastes Great!**

**LUDEN'S.**

*Menthol Lozenge/Oral Anesthetic*

**Honey  
Lemon**

**30 Throat Drops**



**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52183-279
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CORN SYRUP (UNII: 9G5L16BK6N)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCROSE (UNII: C151H8M554)	

**Product Characteristics**

<b>Color</b>	BROWN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	LUDENS
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-279-14	14 in 1 CARTON; Type 0: Not a Combination Product	10/29/2009	08/31/2017

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL	part356	10/29/2009	08/31/2017

**LUDENS HONEY LICORICE THROAT DROPS**

menthol lozenge

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52183-259
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)		MENTHOL	1.0 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
CORN SYRUP (UNII: 9G5L16BK6N)				
GLYCERIN (UNII: PDC6A3C0OX)				
HONEY (UNII: Y9H1V576FH)				
SODIUM ACETATE (UNII: 4550K0SC9B)				
SOYBEAN OIL (UNII: 241ATL177A)				
SUCROSE (UNII: C151H8M554)				
WATER (UNII: 059QF0K00R)				
<b>Product Characteristics</b>				
<b>Color</b>	BLACK	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm	
<b>Flavor</b>	LICORICE	<b>Imprint Code</b>	LUDENS	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:52183-259-14	14 in 1 CARTON; Type 0: Not a Combination Product	10/29/2009	
2	NDC:52183-259-20	20 in 1 BOX; Type 0: Not a Combination Product	10/29/2009	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part356	10/29/2009		

<b>LUDENS HONEY LEMON THROAT DROPS</b>			
menthol lozenge			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52183-269
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)		MENTHOL	1.0 mg
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HONEY (UNII: Y9H1V576FH)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

### Product Characteristics

Color	YELLOW	Score	no score
Shape	CAPSULE	Size	23mm
Flavor	LEMON (Honey Lemon)	Imprint Code	LUDENS
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-269-14	14 in 1 CARTON; Type 0: Not a Combination Product	10/29/2009	08/31/2021
2	NDC:52183-269-30	30 in 1 BAG; Type 0: Not a Combination Product	10/29/2009	08/31/2021

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	10/29/2009	08/31/2021

## LUDENS HONEY LICORICE THROAT DROPS

menthol lozenge

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-255
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.6 mg

### Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	

<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HONEY</b> (UNII: Y9H1V576FH)	

### Product Characteristics

<b>Color</b>	BLACK	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>	LICORICE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-255-30	30 in 1 BAG; Type 0: Not a Combination Product	10/29/2009	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	10/29/2009	

## LUDENS HONEY LEMON THROAT DROPS

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52183-266
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.6 mg

### Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCROSE (UNII: C151H8M554)	
HONEY (UNII: Y9H1V576FH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

SODIUM CHLORIDE (UNII: 451W47IQ8X)

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>	LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-266-30	30 in 1 BAG; Type 0: Not a Combination Product	10/29/2009	08/31/2021

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	10/29/2009	08/31/2021

**Labeler** - Prestige Brands Holdings, Inc. (159655021)

Revised: 6/2020

Prestige Brands Holdings, Inc.