

## **XLEAR COUGH DROPS (HONEY LEMON)- menthol lozenge**

**Xlear 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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**Xlear Cough Drops (Honey Lemon)**

4.0 mg of Menthol (per drop)

Cough Suppressant / Oral Anesthetic

Temporarily soothes an irritated or sore throat

Adults and children over five - Slowly dissolve one drop every two hours as needed or as directed by a physician. Children under five - Consult your physician.

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore throat symptoms do not improve in 7 days, see your doctor promptly

Keep out of reach of children.

**Allergen Information:** Mfg. in a facility that processes dairy, peanut, almond, walnut, nutmeg, pecan, and soy protein.

cinnamon bark oil, clove bud oil, eucalyptus radiata leaf oil, isomalt, lemon peel oil, pectin, peppermint aerial parts oil, rosemary leaf oil, stevia leaf extract, water

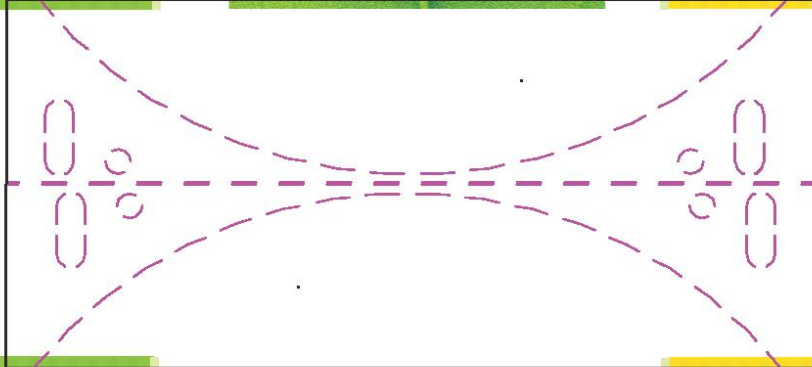
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Artificial  
Tooth  
Friendly



30  
DROPS



TJHILBAQ RT



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BPA-FREE

**XLEAR**

Manufactured for  
Xlear Inc., PO Box 1421  
American Fork, UT 84003 USA  
Customer Service:  
1.877.599.5327  
[WWW.XLEAR.COM](http://WWW.XLEAR.COM)

<b>Drug Facts</b>
<b>Active Ingredients:</b> 4.0 mg of Menthol (per drop) Cough suppressant / Oral anesthetic
<b>Uses:</b> Temporarily soothes an irritated or sore throat
<b>Inactive Ingredients:</b> Isomalt, Malic Acid, Natural Flavors, Stevia, Titanium Dioxide, Xylitol, Xylitol
<b>Directions:</b> Adults and children over five – Slowly dissolve one drop every two hours as needed or as directed by a physician. Children under five – Consult your physician.
<b>Warnings:</b> If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore throat symptoms do not improve in 7 days, see your doctor promptly.
<b>Keep out of reach of children.</b>
<b>Allergen Information:</b> Mfg. in a facility that processes dairy, peanut, almond, walnut, nutmeg, pecan and soy protein.



- FAST RELIEF
- NATURALLY SWEETENED WITH XYLITOL
- SOOTHES AND MOISTURIZES
- HELPS SUPPRESS COUGH

Xylitol-sweetened, menthol-infused drops soothe your irritated throat, while reducing coughs and providing fast relief to dry scratchy tissues. Xlear Cough Drops moisturize dry tissues and don't feed bacteria the way sugar-sweetened drops do. Made with natural xylitol, a clinically proven natural sweetener that improves oral health.

SUGAR FREE COUGH DROPS



## XLEAR COUGH DROPS (HONEY LEMON)

menthol lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27017-022
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>ISOMALT</b> (UNII: S870P55O2W)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>CURCUMA LONGA LEAF</b> (UNII: H2HC4RY52C)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	22mm
<b>Flavor</b>	HONEY (Lemon)	<b>Imprint Code</b>	none
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27017-022-01	30 in 1 BOX; Type 0: Not a Combination Product	12/12/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/12/2019	

**Labeler** - Xlear Inc. (839884058)

## Establishment

Name	Address	ID/FEI	Business Operations
Primrose Candy Company		005086855	manufacture(27017-022)

Revised: 1/2023

Xlear Inc.