XLEAR COUGH DROPS (GREEN APPLE)- 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.

Xlear Cough Drops (Green Apple)

4.0mg of Menthol (per drop)

Cough Suppressant / Oral Anesthetic

Temporarily soothes an irritated or sore throat

Alfalfa, Isomalt, Malic Acid, Natural Apple Flavor, Stevia, Titanium Dioxide, Xytitol

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.

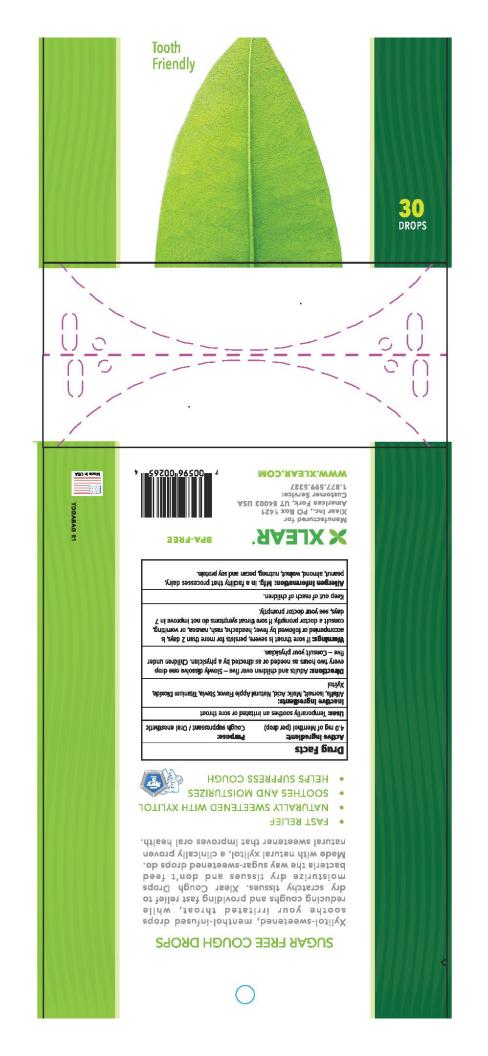
If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore throat symptoms do not improve in 7 days, see your doctor promptly.

Keep out of reach of children.

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

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XLEAR COUGH DROPS (GREEN APPLE)

menthol lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:27017-021

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (LINUX LATICEIDAN) (MENTHOL LINUX ATTOCIDAN)	MENTUOL	4

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 4 mg

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
MALIC ACID (UNII: 817L1N4CKP)	
STEVIA LEAF (UNII: 6TC6NN0876)	
ISOMALT (UNII: S870P55O2W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

ALFALFA (UNII: DJO934BRBD)

Product Characteristics

Color	green	Score	score with uneven pieces
Shape	ROUND	Size	22mm
Flavor	APPLE	Imprint Code	none
Contains			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:27017-021- 01	30 in 1 BOX; Type 0: Not a Combination Product	12/12/2019	

Marketing Information	_	_	_	_
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Marketing Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	12/12/2019	

Labeler - Xlear Inc. (839884058)

Establishment				
Name	Address	ID/FEI	Business Operations	
Primrose Candy Company		005086855	manufacture(27017-021)	

Revised: 1/2023 Xlear Inc.