XLEAR COUGH DROPS (BLACK CHERRY)- 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 (Black Cherry)

4.0 mg of menthol (per drop)

Cough Suppressant / Oral Anesthetic

Temporarily soothes an irritated or sore throat

Bett Juice, Isomalt, Malic Acid, Natural Cherry Flavor, Stevia, Titanium Dioxide, Xylitol

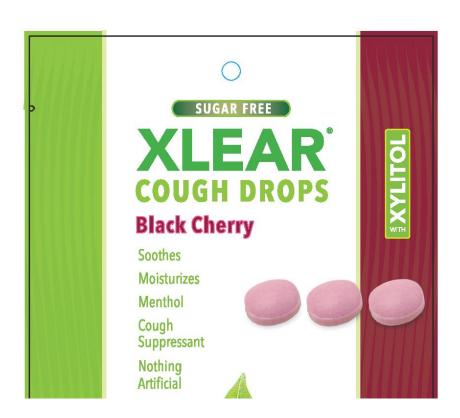
Adults and children over five - Slowly dissolve one drop every two hours as needed or as directed by a physician. Children under five - Consult your physician.

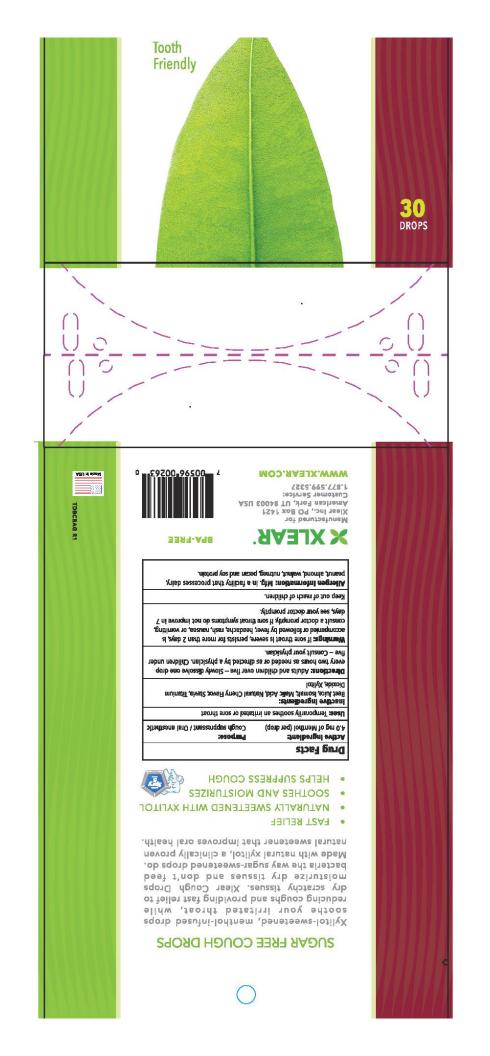
If sore throat is severe, persists for more than 2days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore throat symptoms do not improve in 7 days, see your doctor promptly.

Keep out of reach of children.

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

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XLEAR COUGH DROPS (BLACK CHERRY)

menthol lozenge

Droduc	t Inform	ation
Produc	сиптоги	iation

ISOMALT (UNII: S870P55O2W)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:27017-020

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (LINII: L7T10EIP3A) (MENTHOL - LINII: L7T10EIP3A)	MENTHOL	4 ma

Inactive Ingredients

Ingredient Name
Strength

MALIC ACID (UNII: 817L1N4CKP)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

BEET JUICE (UNII: IOZ 32L9H3O)

XYLITOL (UNII: VCQ006KQ1E)

STEVIA LEAF (UNII: 6TC6NN0876)

Product Characteristics			
Color	pink	Score	score with uneven pieces
Shape	ROUND	Size	22mm
Flavor	CHERRY (Black Cherry)	Imprint Code	none
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:27017-020- 01	30 in 1 BOX; Type 0: Not a Combination Product	12/12/2019	

Marketing In	formation		
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(27017-020)

Revised: 1/2023 Xlear Inc.