# ADVANCED CHERRY FLAVORED COUGH DROPS- cough drops lozenge ADVANCED FIRST AID, 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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### Active Ingredient (in each lozenge) - Menthol 7.6mg

Cough suppressant / Oral anesthetic

**Uses:** temporarily relieves • cough as may occur with a cold • occaional minor irritation 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 symptoms may be serious.

**Ask a doctor before use if you have: •** persistent or chronic cough such as ocurs with smoking, asthma, or emphysema

cough accompanied by excessive phlegm (mucus)

**Stop use and consult a doctor if:** ①• cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

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

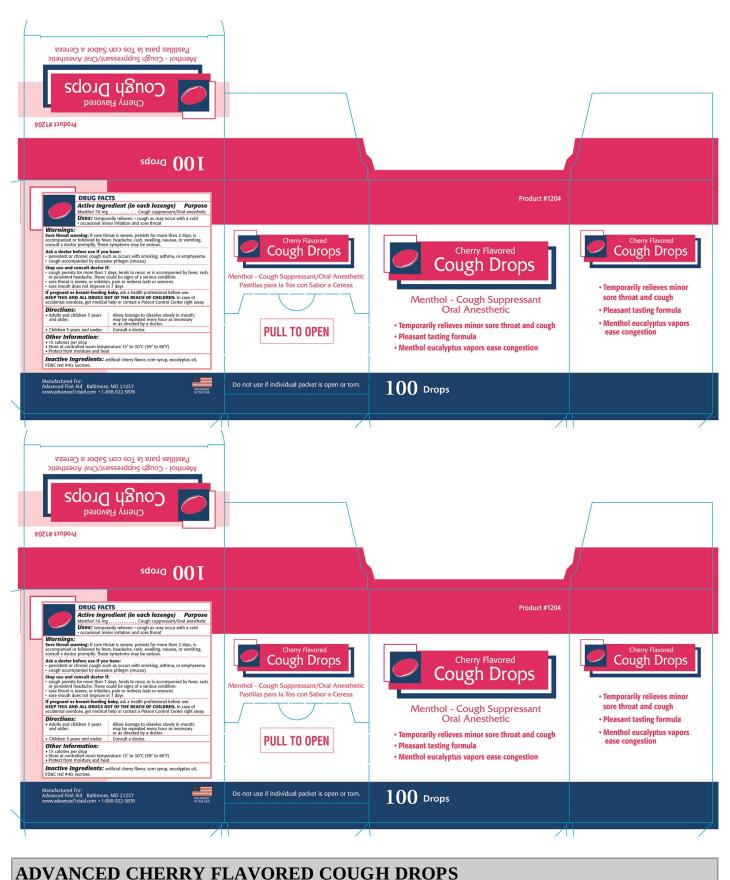
**If pregnant or breast-feeding baby**, ask a health professional before use.

**KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.** In case of accidental overdose, get medical help or contact a Poison Control Center right away.

#### **Directions:**

- **Adults and children 5 years and over:** Allow lozenge to dissolve slowly in mouth; may be repeated every hour as necessary or as directed by a doctor.
- **Children under 5 years:** Consult a doctor.

artificial cherry flavor, corn syrup, eucalyptus oil, FD& C red #40, sucrose



# cough drops lozenge Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67060-120

ORAL

Route of Administration

### Active Ingredient/Active Moiety

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		Ingredient Name		Basis of Strength	Strength
	MENTHOL (UNII: L7T10EII	P3A) (MENTHOL - UNII:L7T10EIP3A)	M	ENTHOL	7.6

Inactive Ingredients				
Ingredient Name	Strength			
SUCRO SE (UNII: C151H8 M554)				
CORN SYRUP (UNII: 9G5L16BK6N)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				

Product Characteristics				
Color	red (BRIGHT RED)	Score	no score	
Shape	OVAL	Size	23mm	
Flavor	CHERRY	Imprint Code	P	
Contains				

Ш	Packaging					
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
	1 NDC:67060-120-74	100 in 1 CARTON	04/02/2019			
	1 NDC:67060-120-01	1 in 1 PACKET; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	04/02/2019		

# Labeler - ADVANCED FIRST AID, INC. (114477180)

# **Registrant -** ADVANCED FIRST AID, INC. (114477180)

Establishment				
Name	Address	ID/FEI	Business Operations	
ULTRA SEAL CORPORATION		085752004	pack(67060-120)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharmaloz Manufacturing, Inc.		067101998	manufacture(67060-120)	

Revised: 8/2019 ADVANCED FIRST AID, INC.