LEADER COUGH DROPS CHERRY FLAVOR - menthol lozenge Cardinal Health

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.

LEADER Cough Drops Cherry Flavor

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Active ingredient (in each drop)

Menthol 5.8 mg

Purpose

Cough suppressant/Oral anesthetic

Uses

temporarily relieves:

- cough as may occur with a cold
- occasional minor irritation and sore throat

Warnings Sore throat warning:

if sore throat is severe, persists for more than 2 days, is accompanied or followed be fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have:

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

When using this product

• do not exceed recommended dosage

Stop use and consult doctor if

- 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

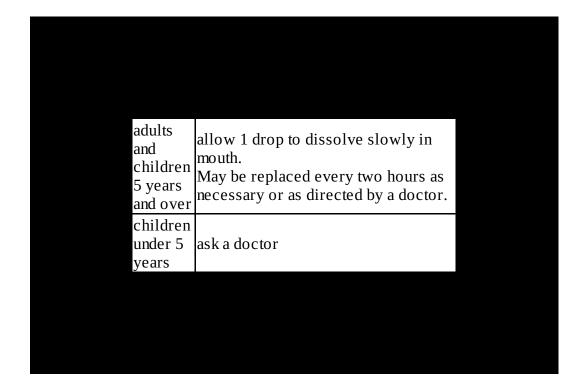
If pregnant or breast-feeding,

ask a health professional before use.

Keep this and all drugs out of the reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions



Other information:

• 10 calories per drop

Inactive ingredients:

Eucalyptus oil, FDandC red no. 40, glucose syrup, NandA flavoring, sucrose and water. Soybean oil and corn starch used as processing aids.

Questions?

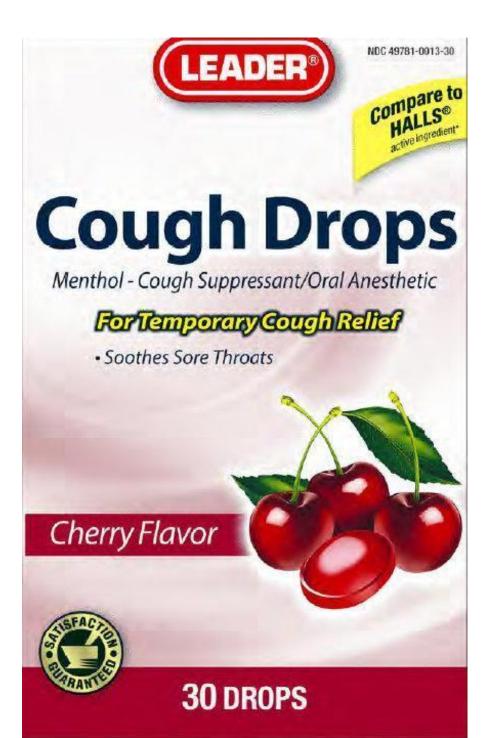
Or to report an adverse event call 1-800-200-6313. Monday - Friday, 9AM to 4PM EST

DISTRIBUTED BY

CARDINAL HEALTH DUBLIN, OHIO 43017 CIN 4830824 www.myleader.com 1-800-200-6313 UD Certified GF Gluten-Free

LEADER Cough Drops Cherry Flavor 30 Count (49781-013-30)

^{*} This product is not manufactured or distributed by Kraft, owner of the registered trademark Halls^R, or by any of its affiliates.





LEADER COUGH DROPS CHERRY FLAVOR

menthol lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49781-013

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	5.8 mg	

Inactive Ingredients				
Ingredient Name	Strength			
EUCALYPTUS OIL (UNII: 2R04ONI662)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
CORN SYRUP (UNII: 9G5L16BK6N)				
SUCROSE (UNII: C151H8 M554)				
WATER (UNII: 059QF0KO0R)				
SO YBEAN OIL (UNII: 241ATL177A)				
STARCH, CORN (UNII: O8232NY3SJ)				

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	12mm	
Flavor	CHERRY	Imprint Code	В	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49781-013-30	30 in 1 BAG			

Marketing Information				
Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/25/2013		

Labeler - Cardinal Health (097537435)

Establishment			
Name	Address	ID/FEI	Business Operations
Bestco, Inc.		002149136	manufacture(49781-013)

Revised: 11/2013 Cardinal Health