

LEADER SUGAR FREE COUGH DROPS BLACK CHERRY- 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 Sugar Free Cough Drops Black Cherry

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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 by 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

adults and children 5 years and over	allow 1 drop to dissolve slowly in mouth. May be replaced every two hours as necessary or as directed by a doctor.
children under 5 years	ask a doctor

Other information:

- 10 calories per drop

Inactive ingredients:

acesulfame potassium, blue no. 1, eucalyptus oil, flavoring, hydrogenated starch hydrolysate, isomalt, red no. 40, sucralose and water. Soybean oil used as a processing aid.

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 4562393 www.myleader.com 1-800-200-6313

UD Certified GF Gluten-Free

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LEADER Sugar Free Cough Drops Black Cherry 25 Count (49781-043-25)

LEADER[®]

NDC 49781-043-25

Compare to
HALLS[®]
active ingredient*

Sugar Free
Cough Drops

Menthol - Cough Suppressant/Oral Anesthetic

For Temporary Cough Relief

- Cools Nasal Passages
- Soothes Sore Throats



Black Cherry



Sweetened with
Splenda[®]
brand

25 DROPS

Drug Facts

Active ingredient (in each drop) *Purposes*
Menthol 5.8 mg.....Cough suppressant/
Oral anesthetic

Uses temporarily relieves:

- cough as may occur with a cold or inhaled irritants
- 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 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 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

Directions
 Adults and children 5 years and over: allow 1 drop to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor.

Children under 5 years: ask a doctor

Other information

- 6 calories per drop
- Store in a cool dry place

Inactive ingredients: acesulfame potassium, blue no. 1, eucalyptus oil, flavoring, hydrogenated starch hydrolysate, isomalt, red no. 40, sucralose and water. Soybean oil used as a processing aid.

Excess consumption may cause laxative effect.



Sugar Free Cough Drops

Menthol - Cough Suppressant/Oral Anesthetic

For Temporary Cough Relief

- Cools Nasal Passages
- Soothes Sore Throats



Black Cherry

All **Leader®** Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Certified



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 DUBLIN, OHIO 43017
 CIN 4562393
 www.myleader.com
 1-800-200-6313

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PH-501108

LEADER SUGAR FREE COUGH DROPS BLACK CHERRY

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4978 1-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)		MENTHOL	5.8 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
ISOMALT (UNII: S870P55O2W)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
WATER (UNII: 059QF0K00R)				
SOYBEAN OIL (UNII: 241ATL177A)				
Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	12mm	
Flavor	CHERRY (Black Cherry)	Imprint Code	B	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-043-25	25 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(49781-043)

Revised: 11/2013

Cardinal Health