

LEADER COUGH DROPS MENTHOL 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 Menthol Flavor

LEADER Cough Drops Menthol Flavor

Active ingredient (in each drop)

Menthol 5.4 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:

Blue flakes (FDandC blue no. 1, glycerin, gum arabic, potassium sorbate), eucalyptus oil, FDandC blue no. 1, FDandC red no. 40, glucose syrup, natural 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 4831053 www.myleader.com 1-800-200-6313

UD Certified GF Gluten-Free

* This product is not manufactured or distributed by Kraft, owner of the registered trademark Halls[®], or by any of its affiliates.

LEADER Cough Drops Menthol Flavor 30 Count (49781-012-30)

LEADER[®]

NDC 49781-0012-30

Compare to
HALLS[®]
active ingredient*

Cough Drops

Menthol - Cough Suppressant/Oral Anesthetic

For Temporary Cough Relief

• *Soothes Sore Throats*

Menthol Flavor



30 DROPS

Drug Facts

Active ingredient (in each drop) Purpose
Menthol 5.4 mg.....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 repeated 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: Blue flakes (FD&C blue no. 1, glycerin, gum arabic, potassium sorbate), eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, glucose syrup, natural 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



Cough Drops

Menthol - Cough Suppressant/Oral Anesthetic

For Temporary Cough Relief

- Soothes Sore Throats

Menthol Flavor



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



Certified



Gluten-Free™

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4831053
www.myleader.com
1-800-200-6313

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



PN-501437

LEADER COUGH DROPS MENTHOL FLAVOR

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4978 1-0 12
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	5.4 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACACIA (UNII: 5C5403N26O)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	
SOYBEAN OIL (UNII: 241ATL177A)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL (Oval)	Size	12mm
Flavor		Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-012-30	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(49781-012)