

PREMIER VALUE- cough drops menthol lozenge
Pharmacy Value Alliance LLC

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.

PV-MGC-YNBY Cough Drops Menthol 30

Active Ingredient(s)

Menthol 5.4 mg

Purpose

Purposes cough suppressant, oral anesthetic

Use

temporary relieves: ■ cough due to cold ■ occasional minor irritation or sore throat

Warnings

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or follow headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These 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).

Stop use and ask a doctor if ■ cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. ■ sore mouth does not improve in 7 days ■ irritation, pain, or redness persists or worsens.

Keep out of reach of children.

Directions

■ adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.

■ children under 5 years: ask a doctor.

Other information

■ 10 calories per drop ■ contains: SOY.

Inactive ingredients

Glucose syrup, sucralose, citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, potassium citrate, sucrose, soy lecithin, water

Or, to report an adverse event, call 800-245-2898.
Monday - Friday, 9 AM to APM EST

Package Label - Principal Display Panel



DRUG FACTS	
Active ingredient (per drop) Menthol 5.4 mg	Purposes cough suppressant, oral anesthetic
Uses temporary relieves: <input type="checkbox"/> cough due to cold <input type="checkbox"/> occasional minor irritation or sore throat	
Warnings Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.	
Ask a doctor before use if you have: <input type="checkbox"/> persistent or chronic cough such as occurs with smoking, asthma, or emphysema <input type="checkbox"/> cough accompanied by excessive phlegm (mucus).	
Stop use and ask a doctor if: <input type="checkbox"/> cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. <input type="checkbox"/> sore mouth does not improve in 7 days <input type="checkbox"/> irritation, pain, or redness persists or worsens.	
Keep out of reach of children.	
Directions <input type="checkbox"/> adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed. <input type="checkbox"/> children under 5 years: ask a doctor.	
Other information <input type="checkbox"/> 10 calories per drop <input type="checkbox"/> contains: SOY.	
Inactive ingredients citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucralose, sucrose, water.	
Questions? Or to report an adverse event call 1-800-245-2898. Monday - Friday, 9AM to 4PM EST	

This product is not manufactured or distributed by the owner of the registered trademark HALLS®

CHOKING WARNING:
NOT FOR CHILDREN UNDER 4.

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



30 Drops NDC: 68016-885-30

PREMIER VALUE

cough drops menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-885
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.4 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CORN SYRUP (UNII: 9G5L16BK6N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	score with uneven pieces
Shape	OVAL	Size	21mm
Flavor	MENTHOL	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-885-30	5.4 in 1 BAG; Type 0: Not a Combination Product	07/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2023	

Labeler - Pharmacy Value Alliance LLC (101668460)**Registrant** - Medical Group Care LLC (085137089)