

COSEDAL DROPS- dextromethorphan hbr, guaifenesin liquid
Menper Distributors, 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.

Active ingredients

Dextromethorphan HBR

Guaifenesin

Purpose

Cough Suppressant

Expectorant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold and help loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Do not exceed recommended dosage.

- A persistent cough may be a sign of a serious condition. If cough persists more than one week, tends to reoccur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not use:

- This product for persistent or chronic cough, such as occurs with smoking, asthma, or emphysema or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Keep out of reach of children.

If you are pregnant or breast-feeding, ask a health professional before use.

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

Directions

Do not exceed 6 doses in 24 hours.

age dose

Adults and children 2 teaspoonfuls (10 mL)

12 years of age and over..... every 4 hours

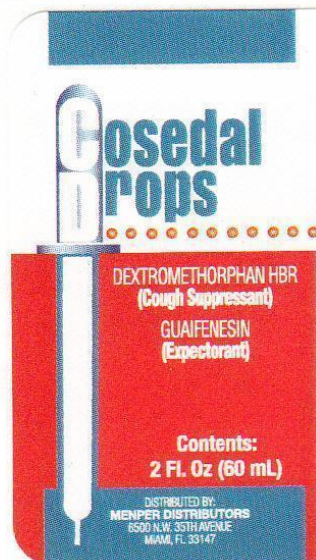
Children 6 to under 1 teaspoonful (5 mL)
 12 years of age..... every 4 hours
 Children 2 to under 1/2 teaspoonful (2.5 mL)
 6 years of age..... every 4 hours
 Children under 2 years of age..... consult your doctor

Other information

Store this product between 15°-30°C (59°-86°F)

Inactive ingredients Citric acid, D&C red #33, glycerin, methylparaben, natural raspberry flavor, propylene glycol, propylparaben, purified water, sucrose

Questions? call 1-800-560-5223 M-F 9 AM to 4 PM Eastern.



Drug Facts

Active ingredients (in each 5 mL)
 Dextromethorphan HBr 10 mg.....Cough suppressant
 Guaifenesin 100 mg.....Expectorant

Uses
 Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold and helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings
Do not exceed recommended dosage. A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.
Do not use
 this product for persistent or chronic cough, such as occurs with smoking, asthma, or emphysema or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor.
 If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's Disease), or for 2 weeks after stopping the MAOI drug, if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
Keep out of reach of children.
If pregnant or breast-feeding, ask a health professional before use. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions
 Do not exceed 6 doses in 24 hours.

age	dose
Adults and children 12 years of age and over	2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children 2 to under 6 years of age	½ teaspoonful (2.5 mL) every 4 hours
Children under 2 years of age	consult your doctor

Other information
 store this product between 15° to 30°C (59° to 86°F)

Inactive ingredients citric acid, D&C red #33, glycerin, methylparaben, propylene glycol, propylparaben, raspberry flavor, sucrose, water

Questions? call 1-800-560-5223 M-F 9 AM to 4 PM Eastern.
 TAMPER-EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED CELLO-BAND OVER CAP IS TORN, BROKEN OR MISSING.

COSEDAL DROPS

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-059
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
RASPBERRY (UNII: 4N14V5R27W)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-059-02	1 in 1 CARTON		
1		60 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

Revised: 9/2013

Menper Distributors, Inc.