

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide liquid
Oncor Pharmaceuticals

Guaifenesin and Dextromethorphan hydrobromide

Active ingredients

(in each 5 mL teaspoonful) Purpose

Dextromethorphan
Hydrobromide 10 mg.....Cough Suppressant
Guaifenesin 200 mg.....Expectorant

Uses

temporarily Relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help you get to sleep

Warnings

Do not exceed recommended dosage.

Do not use this product

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.

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Directions

do not exceed recommended dosage.

adults and children 12 years and over:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours or as directed by a doctor
children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours or as directed by a doctor
children under 6 years of age:	consult a physician

Inactive ingredients

cherry flavor, citric acid, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose.

Other information

- store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature]
- tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Keep out of reach of children.

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.

Principal Display Panel

Oncor Pharmaceuticals

NDC 83720-505-16

Guaifenesin and Dextromethorphan hydrobromide USP

200 mg/10 mg

Expectorant

Cough Suppressant

Non Drowsy - Alcohol Free

For Ages 12 & Up

CHERRY FLAVOR

NET WT. 16 fl. oz. (473 ml)

NDC 83720-505-04

Guaifenesin and Dextromethorphan hydrobromide USP

200 mg/10 mg

Expectorant
Cough Suppressant

Non Drowsy - Alcohol Free

For Ages 12 & Up


CHERRY FLAVOR

NET WT. 4 OZ. (118 ml)

Manufactured In USA For :

Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 12/24

NDC 83720-505-16



Guaifenesin and Dextromethorphan hydrobromide USP

200 mg/10 mg

Expectorant
Cough Suppressant


Non Drowsy - Alcohol Free
For Ages 12 & Up

CHERRY FLAVOR

NET WT. 16 fl. oz. (473 ml)

DRUG FACTS	
<i>Active ingredients (in each 5 mL teaspoonful)</i>	<i>Purpose</i>
Dextromethorphan Hydrobromide 10 mg.....	Cough Suppressant
Guaifenesin 200 mg.....	Expectorant
Uses temporarily Relieves	
<ul style="list-style-type: none"> • cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants • the intensity of coughing • the impulse to cough to help you get to sleep 	
Warnings	
Do not exceed recommended dosage.	
Do not use this product	
<ul style="list-style-type: none"> • 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. 	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema • cough that occurs with too much phlegm (mucus) 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition. 	
If pregnant or breast-feeding, ask a health professional before use.	

DRUG FACTS (continued)	
Directions do not exceed recommended dosage:	
adults and children 12 years and over:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours or as directed by a doctor
children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours or as directed by a doctor
children under 6 years of age:	consult a physician
Inactive ingredients cherry flavor, citric acid, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose.	
Other information	
<ul style="list-style-type: none"> • store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature] • tamper evident by foil seal under cap. Do not use if foil seal is broken or missing. 	
Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.	
Questions? You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.	



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Manufactured in USA For :
Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 12/24

Lot:
Exp:

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83720-505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
CHERRY (UNII: BUC5I9595W)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-505-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025	
2	NDC:83720-505-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2025	

Labeler - Oncor Pharmaceuticals (119032580)**Registrant** - Oncor Pharmaceuticals (119032580)

Establishment

Name	Address	ID/FEI	Business Operations
Quality CDMO		117658386	manufacture(83720-505)

Revised: 1/2025

Oncor Pharmaceuticals