GUAIFENESIN- guaifenesin liquid
Oncor Pharmaceuticals

Guaifenesin Oral Solution USP

Active ingredient (in each 5 mL teaspoonful)

Guaifenesin 100 mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Ask a doctor before use if you have

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

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- do not take more than 6 doses in any 24-hour period

Age	Dose
Adults and Children 12 years and over	2-4 Teaspoonfuls every 4 hours
Children 6 years to under 12 years	1-2 Teaspoonfuls every 4 hours

Children 2 years to under 6 years	1/2-1 Teaspoonful every 4 hours
Under 2 years	Ask a doctor

Drug Facts(continued)

Other information

- store at 20°-25°C (68°-77°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
- sodium content 3 mg/5 mL

Inactive ingredients

Citric acid, Cherry flavor, FD&C red No. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium, sorbitol solution, sucralose.

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.

Manufactured for:
Oncor Pharmaceuticals
8815 Center Park Dr. Suite 430
Columbia, Maryland 21045

Rev. 05/24

PRINCIPAL DISPLAY PANEL

NDC 83720-503-16

ONCOR PHARMACEUTICALS

Guaifenesin

Oral Solution USP

100 mg/5 mL

Expectorant

Relieves Chest Congestion

Sugar Free • Alcohol Free

Cherry Flavor

16 fl. oz. - 473 mL

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8815 Center Park Dr. Suite 430
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Rev. 05/24

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Non Varnished Area

GUAIFENESIN

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83720-503
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (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 (UNII: 9NEZ333N27)	

SORBITOL SOLUTION (UNII: 8KW3E207O2)	
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:83720-503-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/10/2024	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)

Revised: 5/2024 Oncor Pharmaceuticals