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

Guaifenesin and Dextromethorphan hydrobromide

Active ingredients

(in each 5 mL teaspoonful)	Purpose
Dextromethorphan Hydrobromide 10 Guaifenesin 100 mg	

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.

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adults and children 12 2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 years and over:
children 6 to under 12 1 teaspoonful (5 mL) every 4 hours, not to exceed 6 years of age:
children under 6 years
of age:
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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.

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.

Principal Display Panel

Oncor Pharmaceuticals

NDC 83720-501-16

Guaifenesin and Dextromethorphan hydrobromide USP

100 mg/10 mg

Expectorant Cough Suppressant

Non Drowsy - Alcohol Free

For Ages 12 & Up

CHERRY FLAVOR

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

NDC 83720-501-08

Guaifenesin and Dextromethorphan hydrobromide USP

100 mg/10 mg

Expectorant Cough Suppressant

Non Drowsy - Alcohol Free

For Ages 12 & Up

CHERRY FLAVOR

NET WT. 8 OZ. (237 ml)

Manufactured In USA For :

Oncor Pharmaceuticals 6755 Business Pkwy Suite 202 Elkridge, MD 21075 United States. Rev. 02/25

NDC 83720-501-16	DRUG FACTS DRUG FACTS (continued)						
ONCOR	Active ingredients (in each 5 mL teaspoonful) Purpose Dextromethrorphan Hydrobromide 10 mgCough Suppressant Guaifenesin 100 mgExpectorant	Directions do not exceed recommended dosage.					
PHARMACEUTICALS		adults and children 12 years and over:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours	9 9			
Guaifenesin and	Uses temporarily Relieves • cough due to minor throat and bronchial irritation as		or as directed by a doctor 1 teaspoonful (5 mL) every	111			
Dextromethorphan	may occur with the common cold or inhaled irritants • the intensity of coughing • the impulse to cough to help you get to sleep	children 6 to under 12 years of age:	4 hours, not to exceed 6 teaspoonfuls in 24 hours or as directed by a doctor	2015			
hydrobromide Syrup	Warnings Do not exceed recommended dosage.	children under 6 years of age:	consult a physician	837			
100 mg/10 mg	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	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.		-	m		
Expectorant	your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. Other information		°-30°C) [see USP Controlled				
Cough Suppressant Non Drowsy - Alcohol Free	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 ohleam (mucus)	 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. 		Manufactured In USA For : Monufactured In USA For : 6755 Business Pkwy Suite 202 Elkridge, MD 21075 United States. Rev. 02/25			
For Ages 12 & Up	Stop use and ask a doctor if • cough lasts more than 7 days, comes back, or occurs	Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.		sk a doctor if ore than 7 days, comes back, or occurs help or contact a Poison Control Cer	ctured In 1 narmaceuth siness Pkv MD 2107: tates. 25		
CHERRY FLAVOR	with fever, rash or headache that lasts. These could be signs of a serious condition.	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.				anufa ncor Pl 55 Bu kridge, nited S ev. 02/	Lot:
NET WT. 16 II. oz. (473 ml)	If pregnant or breast-feeding, ask a health professional before use.			Z 00225	5,		

NDC 83720-501-08	DRUG FACTS Active ingredients (in each 5 mL teaspoonful) Purpose Dextromethorphan Hydrobromide 10 mgCough Suppressant	DRUG FACTS (continued) Directions do not exceed recommended dosage.		g	
PHARMACEUTICALS	Guaiferiesin 100 mg Expectorant Uses temporarily Relieves • cough due to minor throat and bronchial irritation as may occur with the	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	Area	
Guaifenesin and	common cold or inhaled inflatts the intensity of coughing the intensity of coughing the impulse to cough to help you get to sleep	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	hed	
Dextromethorphan	Warnings Do not exceed recommended dosage.	children under 6 years of age:	consult a physician	nis	
hydrobromide Syrup	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)	Inactive ingredients cherry flavor, citric acid, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium berzoate, 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.		n Varnish	
100 mg/10 mg Expectorant Cough Suppressant	Do not use this product of 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			Non	
Non Drowsy - Alcohol Free For Ages 12 & Up	pharmacist before taking this product. Stop use and ask a doctor if • cough lasts more than 7 days, comes back, or occurs with lever, rash or headache that lasts. These could be signs of a serious condition.	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.			
	If pregnant or breast-feeding, ask a health professional before use.	Oncor Pharmaceutic	Manufactured In USA For : Oncor Pharmaceuticals		
CHERRY FLAVOR NET WT. 8 OZ. (237 ml)	Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.	l overdose, seek professional help or contact a Poison United States. 31883720150108119		Lot: Evn:	

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide syrup liquid

Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:83720-501			
Route of Administration	ORAL						
Active Ingredient/Active Moiety							
Ingred	lient Name		Basis of St	rength	Strength		
DEXTROMETHORPHAN HYDROBE (DEXTROMETHORPHAN - UNII:7355X	-)	DEXTROMETHORE HYDROBROMIDE	PHAN	10 mg in 5 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN		GUAIFENESIN		100 mg in 5 mL			
Inactive Ingredients							
-	Ingredient Name			Stre	ngth		
-	Ingredient Name			Stre	ngth		
CITRIC ACID (UNII: 2968PHW8QP)	-			Stre	ngth		
CITRIC ACID (UNII: 2968PHW8QP) FD&C RED NO. 40 (UNII: WZB9127	-			Stre	ength		
CITRIC ACID (UNII: 2968PHW8QP) FD&C RED NO. 40 (UNII: WZB9127 GLYCERIN (UNII: PDC6A3C0OX)	7XOA)			Stre	ngth		
CITRIC ACID (UNII: 2968PHW8QP) FD&C RED NO. 40 (UNII: WZB9127 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9C WATER (UNII: 059QF0K00R)	7XOA) 2167V3)			Stre	ength		
-	7XOA) 2167V3)			Stre	angth		

CITRIC ACID (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E20702)	
CHERRY (UNII: BUC5I9595W)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
Product Characteristics	

Сс	olor		Score			
Sł	nape			Size		
Fla	avor		CHERRY	Imprint Code		
Co	ontains					
_						
Pa	ackaging					
#	ltem Code	Pa	ackage Description		Marketing Start Date	Marketing End Date
1		473 mL in 1 B Product	BOTTLE; Type 0: Not a Combination		02/01/2025	
2		237 mL in 1 B Product	BOTTLE; Type 0: Not a Combination		02/01/2025	
Μ	Marketing Information					
	Marketing Category	Applica	ation Number or Mon Citation	ograph	Marketing Start Date	Marketing End Date
ОТ	TC Monograph Dru	ig M012			02/01/2025	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)

Revised: 2/2025

Oncor Pharmaceuticals