## DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESINdextromethorphan hydrobromide and guaifenesin syrup OPMX LLC

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Histiacil NF Pentrexicilina NF Brosolvan

## Active Ingredient (in each 5 mL)

**Purpose** 

Dextromethorphan HBr USP 20 mg...... Cough suppressant Guaifenesin, USP 300 mg..... Expectorant

#### Relieves:

- Chest congestion / Mucus
- Cough

#### Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps to loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

# Warnings

 Do not useif 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

- 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
- measure only with dosing cup provided
- ml=milliliter
- this adult product is not intended for use in children under 12 years of age

Age	Dose	
Adults and children 12 years and over	5 mL every 4 hours	
Children under 12 years	do not use	

### Other information

- Store at 20°-25°C (68° -77°F).
- Do not refrigerate.
- Retain carton for future reference on full labeling

## Inactive ingredients

citric acid, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol.

# Questions or comments? Call 619-600-5632

Tamper evident: Do not use if inner seal under cap is broken or missing.

# Exclusively distributed by OPMX

Chula Vista, CA91910 Phone: 619-600-5632

### Manufactured in

FDA Registered Facility In the USA

### PRINCIPAL DISPLAY PANEL PENTREXCILINA ADULT



### PRINCIPAL DISPLAY PANEL BROSOLVAN ADULT



### PRINCIPAL DISPLAY PANEL HISTIACIL ADULT



## DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN

dextromethorphan hydrobromide and quaifenesin syrup



DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-062- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
OTC Monograph Drug	M012	02/01/2021		

# **DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN**

dextromethorphan hydrobromide and guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-020
Route of Administration	ORAL		

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			
MENTHOL (UNII: L7T10EIP3A)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:69729-020- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date			
OTC Monograph Drug	M012	02/01/2021	

# **DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN**

dextromethorphan hydrobromide and guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			
MENTHOL (UNII: L7T10EIP3A)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-040- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2021	

# **Labeler -** OPMX LLC (029918743)

Establishment			
Name	Address	ID/FEI	Business Operations
KJD Pharma Pvt Ltd		877256314	manufacture(69729-062, 69729-040, 69729-020)

Revised: 5/2025 OPMX LLC