

**DEXTROMETHORPHAN HBR, GUAIFENESIN- dextromethorphan hbr,  
guaifenesin capsule, liquid filled  
OPMX LLC**

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**Pentrexilina Expectorant & Cough Suppressant**

Dextromethorphan HBr 20mg

Guaifenesin 400mg

Cough suppressant

Expectorant

FD&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.

Do not take more than directed – See overdose warning

Do not use for more than 7 days

Do not take more than 6 doses in 24 hours

Adults and children 12 years of age and over: take 1 softgel every 4 hours with a full glass of water while symptoms persist

Children under 12 years of age: do not use

Helps loosen phlegm (mucus)

Helps thin bronchial secretions to make coughs more productive

Do not use:

- 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:

- 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 for more than 7 days, recurs, 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.

Keep out of reach of children

**OVERDOSE WARNING:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

store at room temperature between 20-25°C (68-77°F)

avoid excessive heat and humidity



## DEXTROMETHORPHAN HBR, GUAIFENESIN

dextromethorphan hbr, guaifenesin capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-781
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

## Product Characteristics

<b>Color</b>	yellow (LIGHT YELLOW)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	781
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-781-02	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/18/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/18/2019	

**Labeler** - OPMX LLC (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(69729-781)