

**DESPEC DM- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride syrup**  
**International Ethical Laboratories, Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Despec DM**

**Drug Facts**

**Active ingredients ( in each 5 mL teaspoonful)**

Dextromethorphan Hydrobromide 10mg

Guaifenesin 100mg

Phenylephrine Hydrochloride 5mg

**Purpose**

Antitussive/ Expectoant/ Nasal Decongestant

**Uses**

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

**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 emtional 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**

- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic

bronchitis, or emphysema

- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness, occur
- cough or nasal congestion persists for more than 1 week, trends to recur, or persistent headache. A persistent cough may be a sign of a serious condition.
- new symptoms occur

### **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 exceed recommended dosage.

- Use with enclosed dosage cup.

Adults and children 12 years of age and over-----2 teaspoonfuls ( 2 TSP) every 4 hours, not to exceed 6 doses in 24 hours.

Children 6 to under 12 years of age.....1 teaspoonful (1 TSP) every 4 hours, not to exceed 6 doses in 24 hours.

Children under 6 years of age..... Consult a doctor

### **Other information**

Store at room temperature 59°-86°F (15°-30°C)

### **Inactive ingredients**

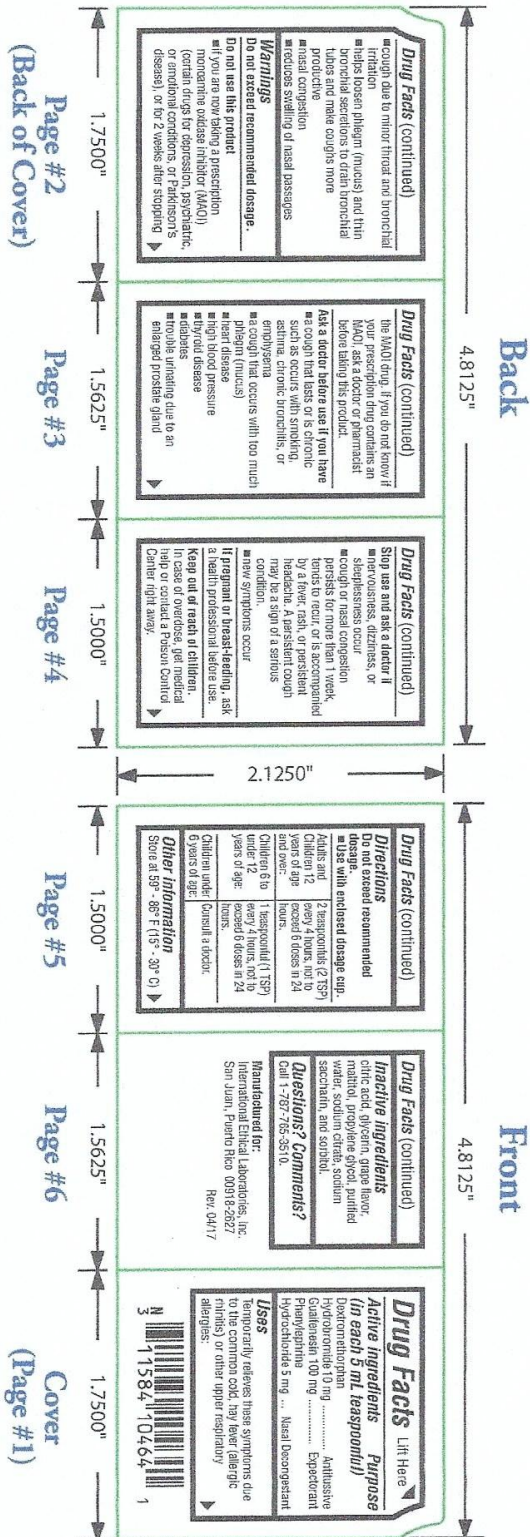
Citric acid, glycerin, grape flavor, maltitol, propylene glycol, purified water, sodium citrate, sodium saccharin and sorbitol.

### **Questions? Comments?**

call 1-787-765-3510

# Principal Display Panel-Label

Booklet



<b>Graphics Proof</b>		Rev#	Date	RT Grade	Artist
Customer: Woodfield Pharmaceutical		13	04/07/17	A	KM
Product Name: 4oz. Despac DM Syrup		14	04/11/17	A	TM
Part #: N/A					
Size (H x W): 2.1250" x 5.0000"					
Date: 04/11/17					
Rev: 1.4					
<b>Copy Position</b>					
#4					
DIE LINE FRONT BLACK BACK BLACK					
Please indicate status below. <input type="checkbox"/> REVISE and RE-PROOF <input checked="" type="checkbox"/> APPROVED APPROVAL SIGNATURE: <i>Elmora</i> DATE: August 1, 2017 APPROVAL SIGNATURE: _____ DATE: _____		THIS PROOF IS NOT INTENDED FOR COLOR REPRESENTATION. PLEASE REVIEW FOR COPY AND POSITIONING OF GRAPHICS AND TEXT.			
PLATINUM PRESS 920 Avenue B, Bldg. 200E General Pkwy., TX 75660 Tel: 409.253.1500 Fax: 409.253.1510 NEW JERSEY 5 Thomson Road, Oakland, NJ 07036 Tel: 908.253.1506 www.platinumpress.com					

Base



Graphics Proof		Rev#	Date	BC Grade	Artist	Copy Position		DIE		RESERVA		APPROVAL		PLATINUM PRESS	
Customer:	Woodfield Pharmaceutical	13	04/07/17	A	KA	#4	DIE LINE	BLACK	PMS 362	PMS 2735	PMS 716	SPOT VARNISH	<input type="checkbox"/> REVISE and RE-PROOF <input checked="" type="checkbox"/> APPROVED		320 Avenue B, 10th Floor NEW JERSEY 5 Thompson Road, Garbanc, NJ 07336 Tel: 908.233.1586 www.platinumpress.com
Product Name:	4oz. Despec DM Syrup	14	04/11/17	A	KA								Please indicate status below: Please sign, date, and return if approved. APPROVAL SIGNATURE: <i>M. Adams</i> DATE: <i>August 1, 2017</i>		
Part #:	N/A												THIS PROOF IS NOT INTENDED FOR COLOR REPRODUCTION. PLEASE REVIEW FOR COPY AND POSITIONING OF GRAPHICS AND TEXT.		
Size (H x W):	2.1250" x 5.0000"														
Date:	04/11/17														
Rev:	1/4														

Principal Display Panel-120 mL Bottle Label

# DESPEC DM

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride syrup

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11584-1046
<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	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11584-1046-4	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/19/2014	

**Labeler** - International Ethical Laboratories, Inc (091176933)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Woodfield Pharmaceutical, LLC		079398730	manufacture(11584-1046)

Revised: 11/2021

International Ethical Laboratories, Inc