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.

DESPEC DM SYRUP

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.

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

Uses

Temporarily relieves these symptoms due to the common cold, high 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

Active Ingredient Purpose

(in each 5mL teaspoonful)

Dextromethorphan Hydrobromide 15mg…. Antitussive

Guaifenesin 100mg …… Expectorant

Phenylephrine Hydrochloride 5mg …….. Decongestant

Keep out of the reach of children. In case of accidental over dose seek professional help or contact a Poison Control Center immediately.

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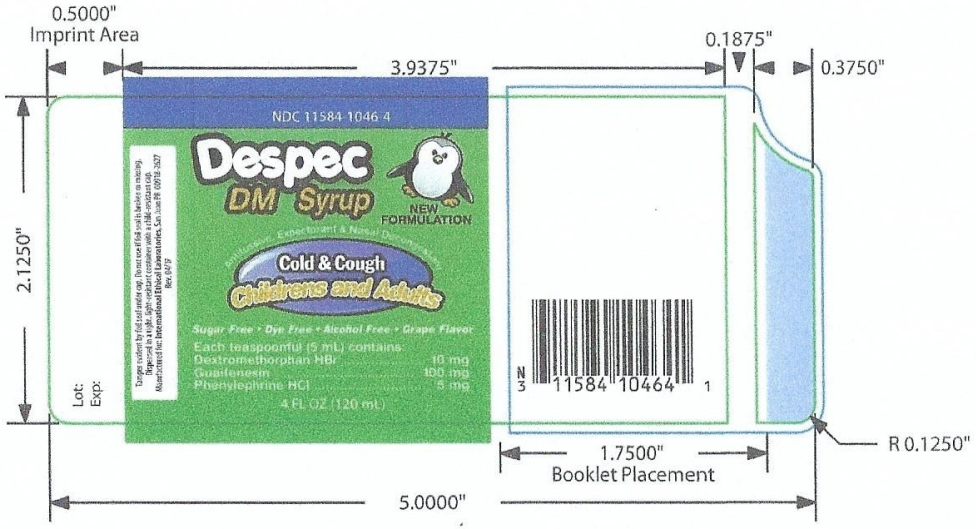
Base



Graphics Proof	Rev.#	Date	BC Grade	Artist
Customer: Woodfield Pharmaceutical	13	04/07/17	A	KH
Product Name: 4oz. Despec DM Syrup	14	04/11/17	A	TA
Part #: N/A				
Size (H x W): 2.1250" x 5.0000"				
Date: 04/11/17				
Rev: 14				

Copy Position

#4

DIE LINE	RESEAL AREA			
BLACK	PMS 362	PMS 2735	PMS 716	SPOT VARNISH

Please indicate status below.
Please sign, date, and return if approved.

☐ REVISE and RE-PROOF ☑ APPROVED

APPROVAL SIGNATURE: M Romero

DATE: August 1, 2017

APPROVAL SIGNATURE:

DATE:

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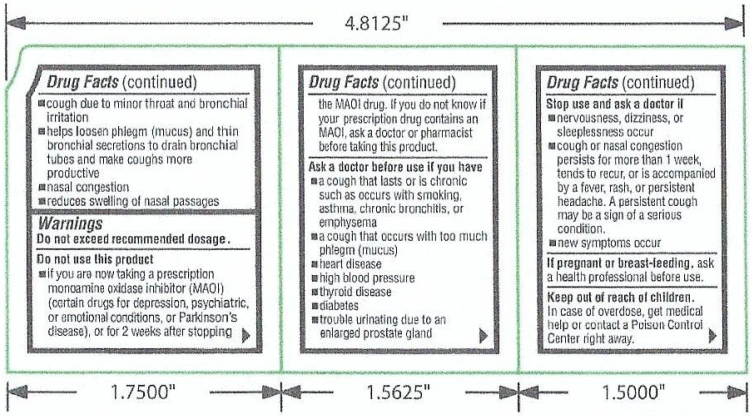
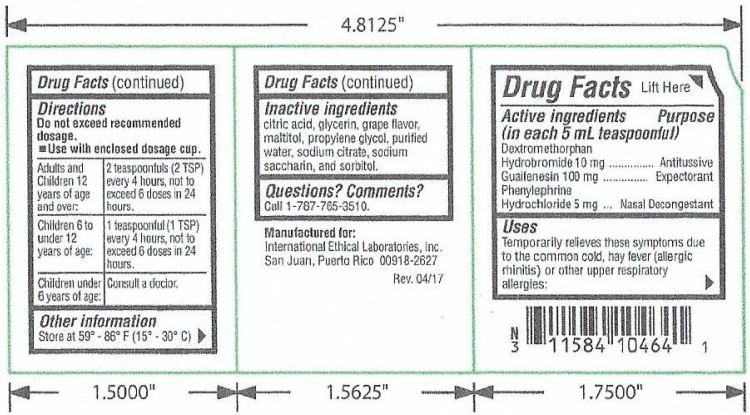
Booklet

Back



Page #2 (Back of Cover) | Page #3 | Page #4

Front



Page #5 | Page #6 | Cover (Page #1)

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DIE LINE | FRONT BLACK | BACK BLACK

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DESPEC DM

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11584-1046
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

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

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11584-1046-5	6 in 1 CARTON	02/19/2014	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	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)

Registrant - Woodfield Pharmaceutical, LLC (079398730)

Establishment

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

Revised: 3/2018 International Ethical Laboratories, Inc.