DESPEC- dextromethorphan hydrobromide, guaifenesin, phenyllephrine hydrochloride liquid
INTERNATIONAL ETHICAL LABS

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-G

Active Ingredient

Active ingredients Purpose

(in each 5 mL teaspoonful)

Dextromethorphan

Hydrobromide 10 mg ..... Antitussive

Guaifenesin 100 mg ..... Expectorant

Phenylephrine

Hydrochloride 5 mg .... Nasal Decongestant

Purpose

Antitussive

Expectorant

Nasal Decongestant

Indications & Usage

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

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.
If pregnant or breast-feeding, ask a health professional before use.

Ask a doctor

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

Stop use and ask a doctor if
nervousness, dizziness, or sleeplessness occur
cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
new symptoms occur

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Dosage & Administration

Do not exceed recommended dosage.
Use with enclosed dosage cup.
Adults and Children 12 years of age and over:
Children 6 to under 12 years of age:
Children under 6 years of age:
2 teaspoonfuls (2 TSP) every 4 hours, not to exceed 6 doses in 24 hours.
1 teaspoonful (1 TSP) every 4 hours, not to exceed 6 doses in 24 hours.
Consult a doctor.

Other safety information

Other information
Store at 59° - 86° F (15° - 30° C)

Inactive ingredient

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

Questions? Comments?

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Call 1-787-765-3510.
Manufactured for:

International Ethical Laboratories

San Juan PR 00918-2627

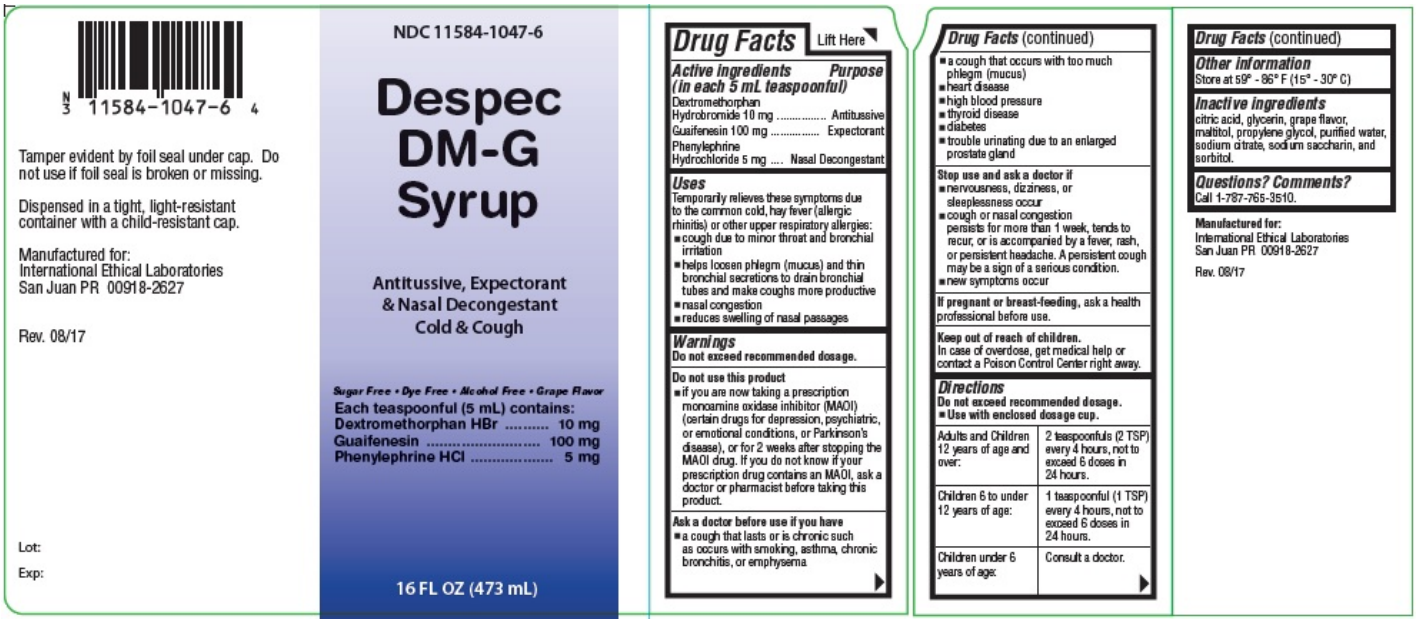
Manufactured by:

Woodfield Pharmaceutical, LLC

Houston, TX 77099

Rev. 09/15

Package Label Principal Display Panel



DESPEC

dextromethorphan hydrobromide, guaifenesin, phenyllephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11584-1047
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	

MALTITOL (UNII: D65DG142WK)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11584-1047-6	1 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/11/2016	

Labeler - INTERNATIONAL ETHICAL LABS (091176933)

Establishment

Name	Address	ID/FEI	Business Operations
WOODFIELD PHARMACEUTICAL, LLC		079398730	manufacture(11584-1047)

Revised: 10/2018 INTERNATIONAL ETHICAL LABS