DESPEC EDA DROPS- dextromethorphan hydrobromide, guaifenesin, phenylephrine 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 EDA Drops

ACTIVE INGREDIENT

Active ingredients:
(in each 1 mL dropperful)
Dextromethorphan Hydrobromide 5 mg
Guaifenesin 50 mg
Phenylephrine Hydrochloride 2.5 mg

PURPOSE

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

in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

ASK DOCTOR

Ask a doctor before use if the child has:

a cough that lasts or is chronic such as occurs with asthma
a cough that occurs with too much phlegm (mucus)
heart disease
high blood pressure
thyroid disease
diabetes

STOP USE

Stop use and ask a doctor if:

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.
nervousness, dizziness, or sleeplessness occur

new symptoms occur

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

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

DOSAGE & ADMINISTRATION

Directions:

Administer using provided dropper.

AGE	DOSE
Children 2 to under 6 years of age:	1 dropperful (1 mL) every 4 hours, not to exceed 6 dropperfuls in 24 hours
Children under 2 years of age:	Consult a physician

INACTIVE INGREDIENT

Inactive ingredients:

Bitter Mask, Citric Acid, Glycerin, Grape Flavoring, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, Sucralose.

OTHER SAFETY INFORMATION

Other information:

Store at 59° - 86°F (15° - 30°C)

QUESTIONS

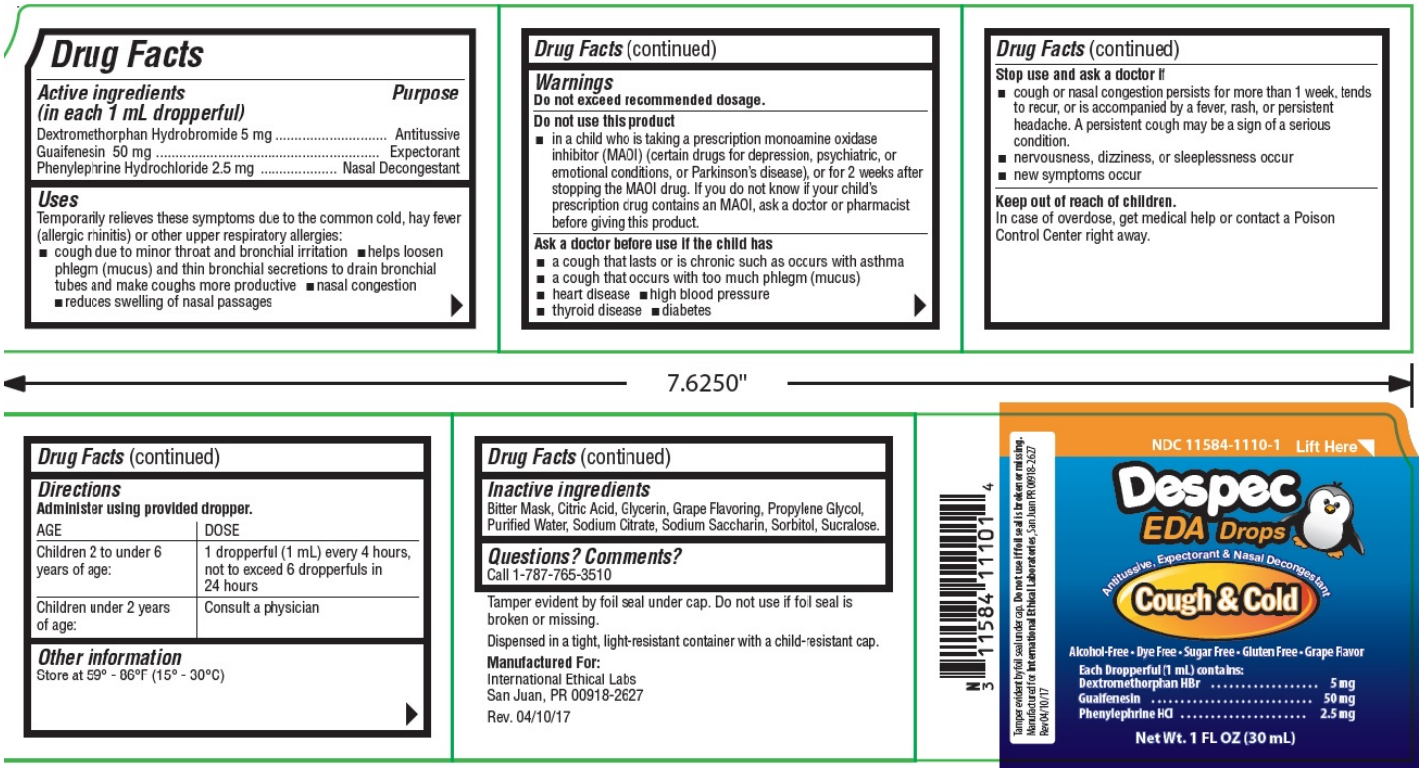
Questions? Comments?

Call 1-787-765-3510

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
Dispensed in a tight, light-resistant container with a child-resistant cap.
Manufactured For:
International Ethical Labs
San Juan, PR 00918-2627

Rev. 04/10/17

Product Packaging



DESPEC EDA DROPS

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11584-1110
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11584-1110-1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/19/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/19/2012	

Labeler - International Ethical Labs (091176933)

Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceuticals, LLC		079398730	manufacture(11584-1110)

Revised: 10/2018 International Ethical Labs