

**ED A-HIST DM- dextromethorphan hydrobromide, chlorpheniramine maleate, and phenylephrine hydrochloride liquid**  
**EDWARDS PHARMACEUTICALS, INC.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**ED A-HIST DM**

**Drug Facts**

<b>Active Ingredients (in each 5 mL teaspoonful)</b>	<b>Purpose</b>
Chlorpheniramine Maleate 4 mg	Antihistamine
Dextromethorphan HBr 15 mg	Antitussive
Phenylephrine HCl 10 mg	Nasal Decongestant

**Uses**

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

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- 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 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.

**Do not use this product, unless directed by a doctor, if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- a persistent or chronic cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease

- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

**Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.**

**When using this product**

- excitability may occur, especially in children
- may cause marked drowsiness
- sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

**Stop use and ask 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. These could be signs of a serious condition.
- new symptoms occur

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

**Directions**

**Do not exceed recommended dosage**

Adults and children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 hours, not to exceed 3 teaspoonfuls in 24 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

**Other information**

Store at 59° - 86° F (15° - 30° C) [see USP for Controlled Room Temperature].

## **Inactive ingredients**

Banana Flavor, Citric Acid, FD&C Blue #1, FD&C Yellow #6, Methyl Paraben, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol Solution 70%, Sucralose.

## **Question? Comments?**

Call 1-800-543-9560

## **PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

**E**

NDC 0485-0171-16

### **ED A-HIST DM**

**Antihistamine • Antitussive  
• Nasal Decongestant**

**Sugar Free • Gluten Free**

**Each teaspoonful (5 mL)  
for oral administration contains:**

Chlorpheniramine Maleate 4 mg

Dextromethorphan HBr 15 mg

Phenylephrine HCl 10 mg

### **Banana Flavor**

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.

**Manufactured for:**

***EDWARDS***

**Pharmaceuticals, Inc.**

**Ripley, MS 38663**

**16oz. (473 mL)**



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## Drug Facts (continued)

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Rev. 01/13



# ED A-HIST DM

dextromethorphan hydrobromide, chlorpheniramine maleate, and phenylephrine hydrochloride liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0485-0171
<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	15 mg in 5 mL
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0171-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/11/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/11/2012	

**Labeler** - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 1/2024

EDWARDS PHARMACEUTICALS, INC.