

**ED A-HIST- chlorpheniramine/phenylephrine 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 LIQUID**

**Drug Facts**

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

Chlorpheniramine Maleate 4mg

Phenylephrine Hydrochloride 10 mg

Alcohol.....5%

**Purpose**

Antihistamine.....Nasal Decongestant

**Uses**

temporarily relieves runny nose and nasal congestion due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis), relieves sneezing, itching of the nose or throat, itchy watery eyes, and reduces swelling of the nasal passages.

**Warnings: Do not exceed recommended dosage.**

**Do not use this product**

- if you are now taking 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 know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

- A breathing problem such as emphysema or chronic bronchitis
- Glaucoma, heart disease, diabetes, high blood pressure or thyroid disease
- Difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

**When using the product**

- May cause drowsiness

- Avoid alcoholic beverages
- Alcohol, sedatives, and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery
- Excitability may occur, especially in children.

**Stop use and ask a doctor if**

- Nervousness, dizziness, or sleeplessness occurs
- Symptoms do not improve within 7 days or are accompanied by a fever.

**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.

Adults and children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	1/2 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in a 24 hour period
Children under 6 years of age:	Consult a Doctor

A special measuring device should be used to give an accurate dose of this product to children under 12 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

**Other information:**

Store at 59° - 86°F (15° - 30°C)

**Inactive ingredients:**

FD and C Blue #1, Grape Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, and FD and C Red #40.

**Questions or comments?**

Call 1-800-543-9560

Iss. 12/10

## **Product Packaging**

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 0485-0155-16

ED A-HIST LIQUID

ANTIHISTAMINE / DECONGESTANT

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

Chlorpheniramine Maleate.....4 mg

Phenylephrine Hydrochloride.....10 mg

Alcohol USP.....5%

GLUTEN FREE / SUGAR FREE

DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING

Manufactured for:

EDWARDS Pharmaceuticals, Inc.

Ripley, MS 38663

Net Contents: 1 pint (473 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Dispense in a tight, light-resistant container with a child-resistant closure.

This bottle is not to be dispensed to consumer.

Manufactured for: Edwards Pharmaceuticals, Inc., Ripley, MS 38663

Iss. 12/10



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## Drug Facts Lift Here

### Active ingredients Purpose (in each 5 mL teaspoonful)

Chlorpheniramine Maleate	4 mg.....	Antihistamine
Phenylephrine Hydrochloride	10 mg ...	Nasal Decongestant
Alcohol	.....	5%

**Uses** temporarily relieves runny nose and nasal congestion due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis), relieves sneezing, itching of the nose or throat, itchy watery eyes, and reduces swelling of nasal passages.

**Warnings:** Do not exceed recommended dosage.

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**Drug Facts (continued)**

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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.

Adults and children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	½ teaspoonful (2.5 mL) every 4 hours, not to exceed 3 teaspoonfuls in a 24 hour period
Children under 6 years of age:	Consult a Doctor

A special measuring device should be used to give an accurate dose of this product to children under 12 years of age. Giving a

**Drug Facts (continued)**

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**Other information:**

Store at 59°-86°F (15°-30°C)

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Iss. 12/10

**ED A-HIST**

chlorpheniramine/phenylephrine liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0485-0155
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9J9Z) (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>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

## 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:0485-0155-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/11/2011	

**Labeler** - Edwards Pharmaceuticals, Inc. (195118880)

## Establishment

Name	Address	ID/FEI	Business Operations
Syntho Pharmaceuticals		088797407	manufacture(0485-0155)

Revised: 1/2024

Edwards Pharmaceuticals, Inc.