

ED A-HIST- chlorpheniramine/phenylephrine liquid
Edwards Pharmaceuticals, Inc.

ED-EDAHISTLIQ 0155

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



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.

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

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ED A-HIST Liquid



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)

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.

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 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

Drug Facts (continued) Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using the product <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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:	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) 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&C Blue #1, Grape Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, and FD&C Red #40.	
Questions or comments? Call 1-800-543-9560	

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ED A-HIST

chlorpheniramine/phenylephrine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0485-0155
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALCOHOL (UNII: 3K9958V90M)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
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
OTC Monograph Drug		M012	01/11/2011	

Labeler - Edwards Pharmaceuticals, Inc. (195118880)