

ED A-HIST- chlorpheniramine maleate and phenylephrine hydrochloride tablet, coated
Dispensing Solutions, Inc.

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.

ED A-HIST TABLETS

Drug Facts

<i>Active Ingredients (in each tablet)</i>	<i>Purpose</i>
Chlorpheniramine Maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal Decongestant

Uses

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

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- 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.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes mellitus
- 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 this product

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

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by a fever
- new symptoms occur

If pregnant or breast-feeding, 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 tablet every 4 hours, not to exceed 6 tablets in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor.

Inactive ingredients

FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate. Contains FD&C Yellow No. 5 (tartrazine) as a color additive

Questions or Comments?

Call 1-800-543-9560 Rev.

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

NDC 66336-0488-XX

ED A-HIST TABLETS

Antihistamine • Nasal Decongestant

Each tablet contains: Chlorpheniramine Maleate 4 mg
Phenylephrine HCl 10 mg

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

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

NDC 66336-0488-30

BULK SOURCE DATA
MFD. FOR: EDWARDS PHARMACEUTICALS, INC.
RIPLEY, MS 38663

PRODUCT ID:
TAN OVAL SCORED TABLET
DEBOSSED E 1

BULK SOURCE NDC: 00485-0254-01
MFR. LOT: XXXXXX
PEDIGREE #: 118694
DISPENSE IN THIS
TIGHT/LIGHT RESISTANT CONTAINER



TAKE _____ TABLET(S)
ORALLY EVERY _____ HOURS
_____ TIMES A DAY. DO NOT EXCEED
RECOMMENDED DOSAGE. AVOID
ALCOHOL. MAY CAUSE DROWSINESS.
USE CAUTION WHEN DRIVING A
VEHICLE OR OPERATING MACHINERY.
DO NOT USE WITH MAOI DRUGS.



ED A-HIST 4 mg/10 mg
XX TABLETS
NDC 66336-0488-XX
PRODUCT # 850-XX

Rev. Date: 06/13

EACH TABLET CONTAINS:
CHLORPHENIRAMINE MALEATE 4 mg
PHENYLEPHRINE HYDROCHLORIDE 10 mg
(PURPOSE: ANTIHISTAMINE/NASAL DECONGESTANT)
FD&C YELLOW No. 5 AND No. 6

LOT# SAMPLE EXP: 00-00 Rx # 33211546

**WARNING: KEEP OUT OF CHILDREN'S REACH
STORE AT 59°- 86° F**

850- XX NDC 66336-0488- XX
ED A-HIST 4 mg/10 mg
XX TABLETS
LOT # SAMPLE EXP: 00-00
MN 00485-0254-01 RX# 33211546

850- XX NDC 66336-0488- XX
ED A-HIST 4 mg/10 mg
XX TABLETS
LOT # SAMPLE EXP: 00-00
MN 00485-0254-01 RX# 33211546

850- XX NDC 66336-0488- XX
ED A-HIST 4 mg/10 mg
XX TABLETS
LOT # SAMPLE EXP: 00-00
MN 00485-0254-01 RX# 33211546



Packaged Exclusively By:
DISPENSING SOLUTIONS Ph.C
Santa Ana, CA 92704

ED A-HIST

chlorpheniramine maleate and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66336-488(NDC:0485-0254)
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	BROWN (WHEAT)	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	E;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66336-488-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/08/2011	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(66336-488) , repack(66336-488)

Revised: 6/2013

Dispensing Solutions, Inc.