ED A-HIST- chlorpheniramine maleate and phenylephrine hydrochloride tablet
Syntho Pharmaceuticals, 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

Active Ingredients (in each tablet)	***Purpose***
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 is 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor.

Inactive ingredients

Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate, HPMC, Propylene Glycol, Tricetin, Titanium Dioxide, Caramel Color, Riboflavin, Yellow Oxide, Lake Blend Black

Questions or Comments?

Call 1-800-664-1490 Rev. 9/22

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 66576 -254-01

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.
Berwyn,PA 19312

100 tablets

ED A-HIST
chlorpheniramine maleate and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66576-254
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	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRICETIN (UNII: 5627PY99ZO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARAMEL (UNII: T9D99G2B1R)	
RIBOFLAVIN (UNII: TLM2976OFR)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	brown	**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:66576-254-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/02/2022	

Labeler - Syntho Pharmaceuticals, Inc. (088797407)

Registrant - Syntho Pharmaceuticals, Inc. (088797407)

Establishment

Name	Address	ID/FEI	Business Operations
Syntho Pharmaceuticals, Inc.		088797407	manufacture(66576-254)

Revised: 11/2022 Syntho Pharmaceuticals, Inc.