

ED-A-HIST PSE- pseudoephedrine hydrochloride and triprolidine hydrochloride tablet, coated
EDWARDS 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 PSE TABLETS

Drug Facts

Active Ingredients (in each tablet)	Purpose
Pseudoephedrine HCl 60 mg	Nasal Decongestant
Triprolidine HCl 2.5 mg.	Antihistamine

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 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 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 4-6 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	1/2 tablet every 4-6 hours, not to exceed 2 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, 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. 11/11

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 00485-0210-01

ED A-HIST PSE TABLETS

Nasal Decongestant • Antihistamine

Each tablet contains:

Pseudoephedrine HCl	60 mg
Triprolidine HCl	2.5 mg

This bottle is not to be dispensed to consumer.
Dispense in a tight, light-resistant container
with a child-resistant cap.

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**

100 tablets



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EDWARDS
Pharmaceuticals, Inc.
Ripley, MS 38863
100 tablets



Lot:
Exp. Date:

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Tripolidine HCl 2.5 mg	Antihistamine

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Peel Here

Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0485-0210
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg

Inactive Ingredients

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

Product Characteristics

Color	green	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	ED;PSE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0210-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/08/2011		

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 1/2022

EDWARDS PHARMACEUTICALS, INC.