ED-A-HIST PSE- pseudoephedrine hydrochloride and tripolidine 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.

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ED-A-HIST PSE TABLETS

Drug Facts

<table>
<thead>
<tr>
<th>Active Ingredients (in each tablet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudoephedrine HCl 60 mg</td>
<td>Nasal Decongestant</td>
</tr>
<tr>
<td>Tripolidine HCl 2.5 mg.</td>
<td>Antihistamine</td>
</tr>
</tbody>
</table>

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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Pharmaceuticals, Inc.
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100 tablets

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(in each tablet)
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Drug Facts (continued)

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

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<thead>
<tr>
<th>Product Information</th>
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<tbody>
<tr>
<td><strong>Product Type</strong></td>
<td>HUMAN OTC DRUG</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>ORAL</td>
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<tr>
<td><strong>Item Code (Source)</strong></td>
<td>NDC:0485-0210</td>
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<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)</td>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>60 mg</td>
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<tr>
<td></td>
<td>TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)</td>
<td>TRIPROLIDINE HYDROCHLORIDE</td>
<td>2.5 mg</td>
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</table>

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<thead>
<tr>
<th>Inactive Ingredients</th>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td></td>
<td>FD&amp;C BLUE NO. 2 (UNII: L06K8R7DQK)</td>
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<td></td>
<td>FD&amp;C YELLOW NO. 5 (UNII: I753WB2F1M)</td>
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<td></td>
<td>MAGNESIUM STEARATE (UNII: 70097M6E30)</td>
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<td></td>
<td>CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)</td>
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<td></td>
<td>SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)</td>
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<thead>
<tr>
<th>Product Characteristics</th>
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<tbody>
<tr>
<td><strong>Color</strong></td>
<td>GREEN</td>
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<tr>
<td><strong>Shape</strong></td>
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<tr>
<td><strong>Flavor</strong></td>
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<tr>
<td><strong>Contains</strong></td>
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<tr>
<td><strong>Score</strong></td>
<td>2 pieces</td>
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<tr>
<td><strong>Size</strong></td>
<td>13mm</td>
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<td><strong>Imprint Code</strong></td>
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<table>
<thead>
<tr>
<th>Packaging</th>
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<tbody>
<tr>
<td>#</td>
<td>Item Code</td>
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Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>10/08/2011</td>
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Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 2/2013

EDWARDS PHARMACEUTICALS, INC.