# ALAHIST PE- dexbrompheniramine maleate, phenylephrine hydrochloride tablet Poly Pharmaceuticals, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### Alahist PE

#### **Active Ingredients**

(in each tablet)
Dexbrompheniramine Maleate 2 mg
Phenylephrine Hydrochloride 7.5 mg

#### **Purpose**

Dexbrompheniramine Maleate- -Antihistamine Phenylephrine Hydrochloride-- 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, water eyes
- nasal congestion
- reduces swelling of nasal passages

#### **Warnings**

#### 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
- trouble urinating due to enlargement of the prostate gland
- heart disease

- high blood pressure
- thyroid disease
- diabetes

## 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
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery

#### Stop use and Ask Doctor if

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

#### If Pregnant or Breastfeeding

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**

| Adults and children 12 years | 1 tablet every 4 hours, not to exceed 6 tablets in 24   |
|------------------------------|---|
| of age and over:             | hours, or as directed by a doctor.                      |
| Children 6 to under 12 years | 1/2 tablet every 4 hours, not to exceed 3 tablets in 24 |
| of age                       | hours, or as directed by a doctor.                      |
| Children under 6 years of    | Consult a doctor.                                       |
| age:                         | Consuit a doctor.                                       |

#### Other Information

Store at 15°-30°C (59°-86°F). Supplied in a tight, light-resistant container with a child-resistant cap. Alahist PE Tablets are dark purple, caplet-shaped, scored tablets, debossed "Poly" bisect "782" on one side and plain on the other.

#### Inactive ingredients

Croscarmellose sodium, D&C Red # 27 aluminum lake, FD&C Blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide

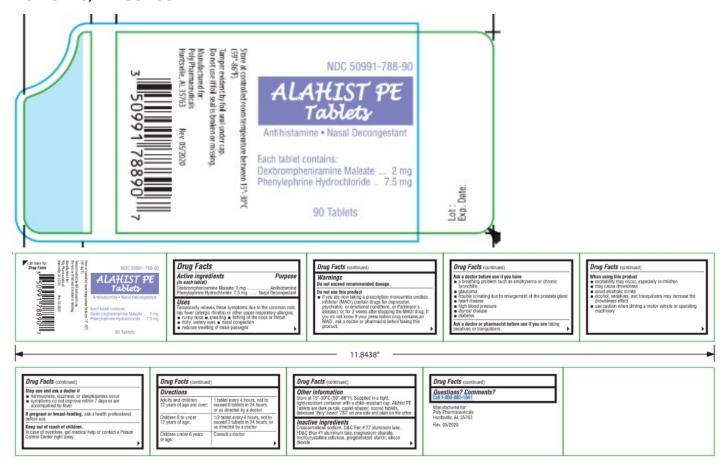
#### **Questions? Comments?**

Call 1-800-882-1041

#### **Alahist PE Label**

Manufactured for

Poly Pharmaceuticals Huntsville, AL 35763



#### **ALAHIST PE**

dexbrompheniramine maleate, phenylephrine hydrochloride tablet

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:50991-788 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety   |                                |          |  |
|---|--------------------------------|----------|--|
| Ingredient Name   | Basis of Strength              | Strength |  |
| <b>DEXBROMPHENIRAMINE MALEATE</b> (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP) | DEXBROMPHENIRAMINE MALEATE     | 2 mg     |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)          | PHENYLEPHRINE<br>HYDROCHLORIDE | 7.5 mg   |  |
|   |                                |          |  |

| Inactive Ingredients                          |          |  |  |
|---|----------|--|--|
| Ingredient Name                               | Strength |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)         |          |  |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)            |          |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |          |  |  |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48)      |          |  |  |
| STARCH, CORN (UNII: O8232NY3SJ)               |          |  |  |
| <b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)  |          |  |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |          |  |  |

| Product Characteristics |         |              |          |  |
|-------------------------|---------|--------------|----------|--|
| Color                   | purple  | Score        | 2 pieces |  |
| Shape                   | CAPSULE | Size         | 11mm     |  |
| Flavor                  |         | Imprint Code | Poly;782 |  |
| Contains                |         |              |          |  |

| F | Packaging            |   |                         |                       |  |  |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | tem Code             | Package Description                                     | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| 1 | NDC:50991-<br>788-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product       | 08/24/2020              |                       |  |  |
| 2 | NDC:50991-<br>788-02 | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | 08/24/2020              |                       |  |  |

| Marketing Information    |   |                         |                       |
|--------------------------|---|-------------------------|-----------------------|
| Marketing<br>Category    | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| unapproved drug<br>other |   | 08/24/2020              |                       |
|                          |   |                         |                       |

### **Labeler -** Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.