**ED-A-HIST DM- chlorpheniramine maleate, dextromethorphan hydrobromide, 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.*

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**ED A-HIST DM TABLETS**

***Drug Facts***

| ***Active Ingredients (in each tablet)*** | ***Purpose*** |
|---|---|
| Chlorpheniramine Maleate 4 mg | Antihistamine |
| Dextromethorphan HBr 10 mg | Antitussive |
| Phenylephrine HCl 10 mg | Nasal Decongestant |

***Uses***

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

- runny nose.
- sneezing.
- itching of the nose or throat.
- itchy, watery eyes.
- cough due to minor throat and bronchial irritation.
- 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.

**Do not use this product, unless directed by a doctor, if you have**

- a breathing problem such as emphysema or chronic bronchitis.
- glaucoma.
- a persistent or chronic cough that occurs with too much phlegm (mucus).
- heart disease.
- high blood pressure.
- thyroid disease.
- diabetes mellitus.

- difficulty in urination due to enlargement of the prostate gland.

**Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.**

**When using this product**
- excitability may occur, especially in children.
- may cause marked drowsiness.
- 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.
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms occur.

**If pregnant or breastfeeding,** 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*

Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate, HPMC, Propylene Glycol, Titanium Dioxide, D&C Red #27, Blue #1.

### *Questions or Comments?*

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

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 66576-240-01

**ED A-HIST DM TABLETS**

Antihistamine • Antitussive • Nasal Decongestant

**Each tablet contains:**

Chlorpheniramine Maleate ..... 4 mg
Dextromethorphan HBr..... 10 mg
Phenylephrine HCl..... 10 mg

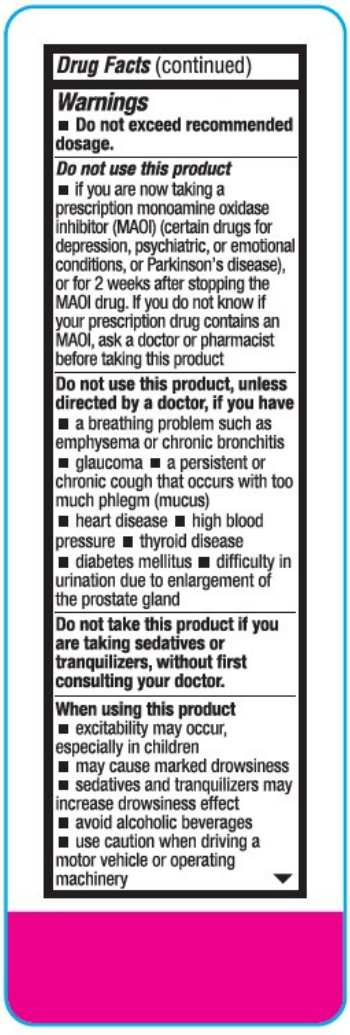
Store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature].
Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

**Manufactured for:**
***EDWARDS***
**Pharmaceuticals, Inc.**
**Berwyn, PA 19312**

**100 tablets**

FRONT


BACK OF FRONT

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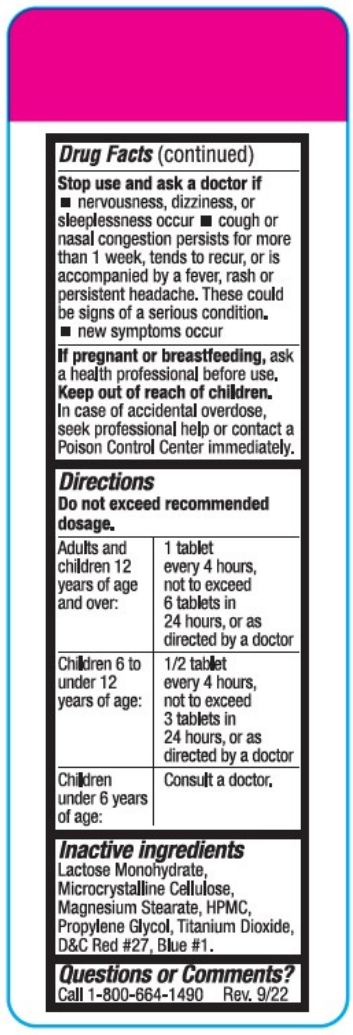

# ED-A-HIST DM

chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:66576-240 |
| **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 |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 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) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | purple | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | ED;DM |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:66576-240-01 | 100 in 1 BOTTLE; 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(66576-240) |

Revised: 11/2022 Syntho Pharmaceuticals, Inc.