ED-A-HIST DM- chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated
EDWARDS 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.

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

Lake blend purple, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or Comments?

Call 1-800-543-9560 Rev. 08/14

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 0485-0240-01

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.
Ripley, MS 38663

100 tablets

Lot:
Exp. Date:

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Peel Here

Drug Facts (continued)

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chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0485-0240
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

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:0485-0240-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/27/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/27/2014	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 1/2024 EDWARDS PHARMACEUTICALS, INC.