DECONEX DMX- dextromethorphan hydrobromide, guaifenesin, 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.

DECONEX DMX TABLETS

Drug Facts

Active ingredients (in each tablet)

Dextromethorphan HBr 17.5 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purpose

Cough Suppressant Expectorant Nasal Decongestant

Uses

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

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- 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 cough that lasts or is chronic such as occurs with smoking, asthma, chronic

bronchitis, or emphysema

- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

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. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast feeding, 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

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
Children 6 to under 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours
Children under 6 years of age:	Consult a physician.

Other information

Store at 15°- 30° C (59°- 86° F).

Supplied in a tight, light-resistant container with a child-resistant cap.

Deconex DMX Tablets are orange, oblong, capsule-shaped, scored tablets, debossed "POLY" bisect "730" on one side and blank on the other side.

Inactive ingredients

Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, Hypromellose, Maltodextrin, Povidone, Silicified

Microcrystalline Cellulose, and Stearic Acid.

Questions? Comments?

Call 1-800-882-1041.

Manufactured for:

Poly Pharmaceuticals

Huntsville, AL

1(800) 882-1041

Rev: 06/19

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel and side panel for 100 tablets label:

NDC 50991-740-01

DECONEX DMX

TABLETS

COUGH SUPPRESSANT · EXPECTORANT

NASAL DECONGESTANT

Each tablet contains:

Dextromethorphan HBr......17.5 mg

Guaifenesin......400 mg

Phenylephrine HCl......10 mg

Tamper evident by foil seal under cap.

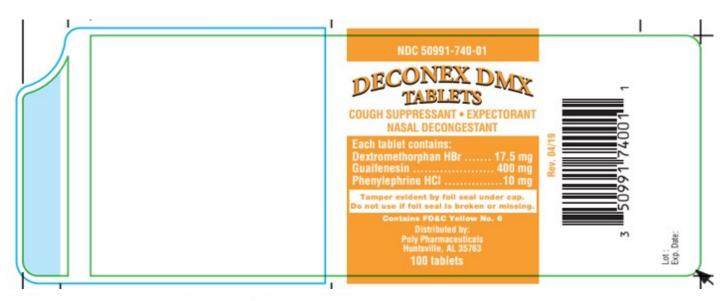
Do not use if foil seal is broken or missing.

Distributed by:

Poly Pharmaceuticals Huntsville, AL

100 tablets

Rev. 06-19





DECONEX DMX

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-740
Route of Administration	ORAL		
Active Incurationt/Active			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	17 5

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	17.5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
POVIDONE (UNII: FZ 989GH94E)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics				
Color	orange	Score	2 pieces	
Shape	CAPSULE	Size	17mm	
Flavor		Imprint Code	POLY;730	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50991-740- 02	12 in 1 CARTON	06/01/2019		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:50991-740- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2019	
otner			

Labeler - Poly Pharmaceuticals, Inc. (198449894)