NIVANEX DMX- guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet
Nivagen 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.

Nivanex DMX™

Drug Facts

Active ingredients (in each Tablet)	***Purpose***
Dextromethorphan HBr 15 mg	Cough Suppressant
Guaifenesin 380 mg	Expectorant
Phenylephrine HCl 10 mg	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 controlled room temperature 15º - 30ºC (59º-86ºF).

Inactive ingredients

D&C Yellow # 10, FD&C Yellow # 6, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate.

Distributed by: Nivagen Pharmaceuticals, Inc
Sacramento, CA 95827 USA
Customer Service Number: 1-877-977-0687

PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Label

NDC 75834-040-60

NIVAGEN
PHARMACEUTICALS

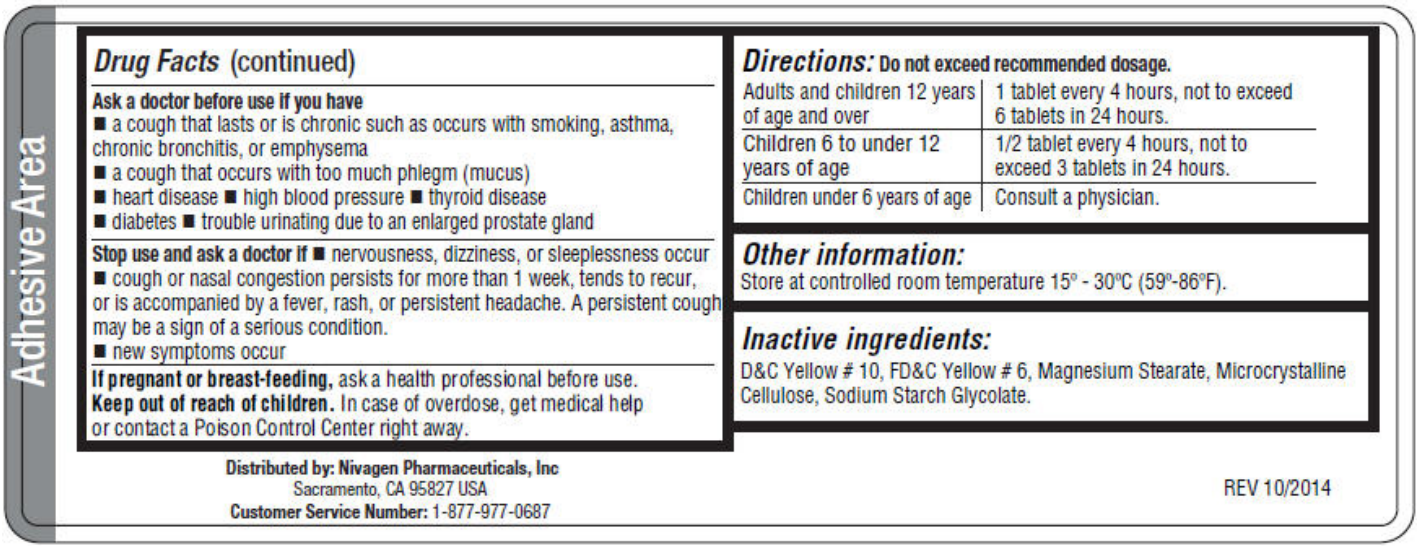
Nivanex DMX™

COUGH SUPPRESSANT • EXPECTORANT
NASAL DECONGESTANT

EACH TABLET CONTAINS:
Dextromethorphan HBr
15 mg
Guaifenesin
380 mg
Phenylephrine HCl
10 mg

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing

60 TABLETS



NIVANEX DMX

guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75834-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	380 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	YELLOW	**Score**	2 pieces
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	N040
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75834-040-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/24/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/24/2014	

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 2/2022 Nivagen Pharmaceuticals, Inc.