# 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.

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#### Nivanex DMX<sup>™</sup>

### **Drug Facts**

Active ingredients (in each Tablet)	Purpose		
Dextromethorphan HBr	Cough		
15 mg	Suppressant		
Guaifenesin 380 mg	Expectorant		
Phenylephrine HCl 10 mg	Nasal		
Filenylepinine HCI 10 Hig	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.

	1 tablet every 4 hours, not
12 years of age	to exceed 6 tablets in 24
and over	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 15° - 30°C (59°-86°F).

#### 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<sup>™</sup>

#### COUGH SUPPRESSANT • EXPECTORANT NASAL DECONGESTANT

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

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

## **60 TABLETS**



Drug Facts (continued) 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	Directions: Do not exceed Adults and children 12 years of age and over Children 6 to under 12	1 tablet every 4 hours, not to exceed 6 tablets in 24 hours. 1/2 tablet every 4 hours, not to
<ul> <li>a cough that occurs with too much phlegm (mucus)</li> <li>heart disease          high blood pressure          thyroid disease         diabetes          trouble urinating due to an enlarged prostate gland</li> </ul>	years of age Children under 6 years of age	exceed 3 tablets in 24 hours.
Stop use and ask a doctor if an ervousness, 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	<b>Other information:</b> Store at controlled room temperature 15° - 30°C (59°-86°F).	
nay be a sign of a serious condition. I new symptoms occur I pregnant or breast-feeding, ask a health professional before use. I pregnant of reach of children. In case of overdose, get medical help r contact a Poison Control Center right away.	Inactive ingredients	w # 6, Magnesium Stearate, Microcrystallin
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## **NIVANEX DMX**

guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet

HUMAN OTC DRUG       MDC:75834-040         NDC:75834-040         OPAL         Active Ingredient/Active Moiety         Basis of Strength       Strength         Strength       Strength         Strength       Strength         Strength       Strength         Strength       DistromethorPhan       US:75834-040         Opale       Strength         Strength         Strength         Strength       Strength         Strength         Strength       Strength         Strength       Strength         Strength       Strength         Strength       Strength         Strength		oduct Inform	mation							
Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strengt GUAIFENESIN (UNII: 4954745(UN) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN 380 mg DeXTROMETHORPHAN HYDROBROMIDE (UNII: 902RT19KYH) DEXTROMETHORPHAN HYDROBROMIDE (UNII: 302RT19KYH) DEXTROMETHORPHAN - UNII:735S3ROTS) DEVTROMETHORPHAN - UNII:735S3ROTS) DEVENDE - PHENVLEPHRINE - PHENVLEPHRINE - HYDROCHLORIDE 10 mg Infactive Ingredients DIFFERENTIAL - UNII:735S3ROTS) DEVENDE - UNII:10079706300 DEVENDE - UNII: 3059706300 DEVENDE - UNII: 3059706300 DEVENDE - UNII: 70079706300 DEVENDE - UNII: 70079706300 DEVENDE - UNII: 001782D61U) DEVENDE - UNII: 001782D61U) DEVENDE - UNII: 001782D61U) DEVENDE - UNII: 001782D61U DEVENDE - UNII: 001782D71E	Pro	oduct Type		HUMAN OTC DRU	G Ite	m Code (	Source)	NDC:7583	75834-040	
Ingredient Name     Basis of Strength     Strength       GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)     GUAIFENESIN     380 mg       DEXTROMETHORPHAN HYDROBROMIDE (UNII: 922RT19KYH)     DEXTROMETHORPHAN HYDROBROMIDE (UNII: 922RT19KYH) <t< td=""><td>Ro</td><td>ute of Adminis</td><td>stration</td><td>ORAL</td><td></td><td></td><td></td><td></td><td></td></t<>	Ro	ute of Adminis	stration	ORAL						
Ingredient Name       Basis of Strength       Strength         GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)       GUAIFENESIN       380 mg         DEXTROMETHORPHAN HYDROBROMIDE (UNII: 92ZRT19KYH)       DEXTROMETHORPHAN HYDROBROMIDE (UN										
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)       GUAIFENESIN       380 mg         DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH)       DEXTROMETHORPHAN HYDROBROMIDE (UNII: 04/A59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE (UNII: 04/A59TNSJ)) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE (UNII: 04/A59TNSJ)) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE (UNII: 04/A59TNSJ)) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE (UNII: 355W5USQ3G)       10 mg         Inactive Ingredients       Strength         Ingredient Name       Strength         DéC YELLOW NO. 10 (UNII: 355W5USQ3G)         FPAC YELLOW NO. 6 (UNII: 177VE193A8)         MAGNESIUM STEARATE (UNII: 70097M6I30)       ImmicRoCRYSTALLINE CELLULOSE (UNII: 071R32D61U)       ImmicRoCRYSTALLINE CELLULOSE (UNII: 071R32D61U)         Product Characteristics         Color       YELLOW       Score       2 pieces         Shape       OVAL       Size       16mm         Imprint Code       N040         Packaging         # Item Code       Package Description       Marketing Start       Marketing End Date         1 NDC:75834-040-       60 in 1 BOTTLE; Type 0: Not a Combination       11/24/2014       11/24/2014       Dete	Ac	tive Ingredie	ent/Active	e Moiety						
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 902RT19KYH)       DEXTROMETHORPHAN HYDROBOMIDE (UNII: 35 mg       15 mg         DIEXTROMETHORPHAN - UNII: 7355X3R0T5)       PHENVLEPHRINE + PHENVLEPHRINE - PHENVLEPHRINE - PHENVLEPHRINE + HYDROCHLORIDE       10 mg         Inactive Ingredients       Ingredient Name       Strength         DSC YELLOW NO. 10 (UNII: 355W5U5Q3G)       FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       Image: Strength         MagNesium STEARATE (UNII: 70097M6I3O)       Image: Strength       Image: Strength         MICROCRYSTALLINE CELLULOSE (UNII: 0PIR32D61U)       Image: Strength       Image: Strength         Product Characteristics       Size       Image: Strength         Flavor       YELLOW       Score       2 pieces         Shape       OVAL       Size       Image: Strength         Flavor       Imprint Code       N040       Image: Strength         Packaging       YelloW       Score       2 pieces         #       Item Code       Package Description       Marketing Start       Marketing End         1       NDC: 75834-040 <sup>-</sup> 60 in 1 BOTTLE; Type 0: Not a Combination       11/24/2014       Image: Start       Marketing End         Marketing Information       Citation       Natesting Start       Marketing End       Date         OTC MONOGRAPH       Application Nu			Ingr	edient Name			Basis of St	rength	Strengt	
IDEXTROMETHORPHAN - UNII: 7355X3ROTS)       HYDROBROMIDE       IS mg         PHENYLEPHRINE HYDROCHLORIDE (UNII: 04jA59TNS)) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE       10 mg         Inactive Ingredients       Ingredient Name       Strength         Bac       Ingredient Name       Strength         Dac       YELLOW NO. 10 (UNII: 355W5USQ3G)       FDac         FDac YELLOW NO. 6 (UNII: H77VEI93A8)       MAGNESIUM STEARATE (UNII: 70097M6I30)       Ingredient Stearate (UNII: 70097M6I30)         MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)       Ingredient Code       2 pieces         Shape       OVAL       Size       16mm         Flavor       Imprint Code       N040         Contains       Ingredient Combination       11/24/2014         Marketing Information       11/24/2014       Marketing Start         Marketing Information       Citation       Marketing Start       Marketing End Date         Marketing Category       Application Number or Monograph       Marketing Start       Marketing End Date						VQ)	GUAIFENESIN		380 mg	
UNII:1W5 297W6MV) HYDROCHLORIDE HYDROCHLORIDE HYDROCHLORIDE HYDROCHLORIDE HYDROCHLORIDE STRENGT STREN	(DE	XTROMETHORPHA	AN - UNII:735	5X3ROTS)				PHAN	15 mg	
Ingredient Name       Strength         D&C YELLOW NO. 10 (UNII: 355 W5U5Q3G)         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       Imprint Code         Packaging         # tem Code       Package Description       Marketing Start Date       Marketing Start Date         Tipon       Marketing Start Date       Marketing Start Date         Marketing Information         Marketing Application Number or Monograph Date       Marketing Start Date       Marketing Start Date			YDROCHLO	RIDE (UNII: 04JA59T	NSJ) (PHENYLI	EPHRINE -			10 mg	
Ingredient Name       Strength         D&C YELLOW NO. 10 (UNII: 355W5U5Q3G)         FD&C YELLOW NO. 6 (UNII: H77VE193A8)         MAGNESIUM STEARATE (UNII: 70097M6130)         MAGNESIUM STEARATE (UNII: 70097M6130)         MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         Product Characteristics         Color       YELLOW       Score       2 pieces         Shape       OVAL       Size       Imprint Code         Packaging         # tem Code       Package Description       Marketing Start Date       Marketing Start Date         Imprint Code       Marketing Start Date       Marketing Start Date         Marketing Information         Marketing Application Number or Monograph Date       Marketing Start Date       Marketing Start Date										
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MAGNESIUM STEARATE (UNII: 70097M6I30) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) Product Characteristics Color YELLOW Score 2 pieces Shape OVAL Size 16mm Flavor Imprint Code N040 Contains N040 Packaging # Item Code Package Description Marketing Start Date 1 NDC:75834-040- 60 in 1 BOTTLE; Type 0: Not a Combination 11/24/2014 Marketing Information Marketing Application Number or Monograph Marketing Start Marketing End Date DTC MONOGRAPH part341 11/24/2014										
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         Product Characteristics         Color       YELLOW       Score       2 pieces         Shape       OVAL       Size       16mm         Flavor       Imprint Code       N040         Contains       Imprint Code       Marketing Start       Marketing End Date         Packaging       Volto       Marketing Start       Marketing End Date         NDC:75834-040-       60 in 1 BOTTLE; Type 0: Not a Combination       11/24/2014       Marketing Start       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start       Marketing End Date         Marketing Lategory       Application Number or Monograph Citation       Marketing Start       Marketing End Date			•	·						
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Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 2/2022

Nivagen Pharmaceuticals, Inc.