ACTIDOM DMX- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution
Actipharma, 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.

ACTIDOM DMX

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 30 mg
Guaifenesin, 200 mg
Phenylephrine HCl, 10 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Uses • Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes • Temporarily relieves these symptoms occurring with a cold: nasal congestion, cough due to minor throat and bronchial irritation.

Warnings • **Do not use** 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 • diabetes • heart disease • thyroid disease • high blood pressure • trouble urinating due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

When using this product • do not exceed recommended dosage

Stop use and ask a doctor if • you get nervous, dizzy or sleepless • symptoms do not get better within 7 days or are accompanied by fever • coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Directions • do not take more than 4 doses in any 24-hour period.

Adults and Children 12 years of age and	5 mL (1tsp), every 6

over	hours
Children under 12 years of age	ask a doctor

Inactive ingredients: Citric acid, D&C Red 40, FD&C Blue#1, flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Other information • Store at room temperature 15° - 30°C (59° - 86°F) • protect from freezing • protect from light • Avoid excessive heat or humidity. TAMPER EVIDENT: Do not use if inner seal is torn, broken or missing.

Manufactured in the USA for ActiPharma, Inc. Dorado, PR 00646. Tel: (787)608-0882

*** Dometuss-DMX® is a registered trademark of Domel Laboratories. This product is not manufactured, distributed or marketed by Domel Laboratories.**

Contains the same active ingredients as Dometuss®-DMX*

COUGH SUPPRESSANT

EXPECTORANT

NASAL DECONGESTANT

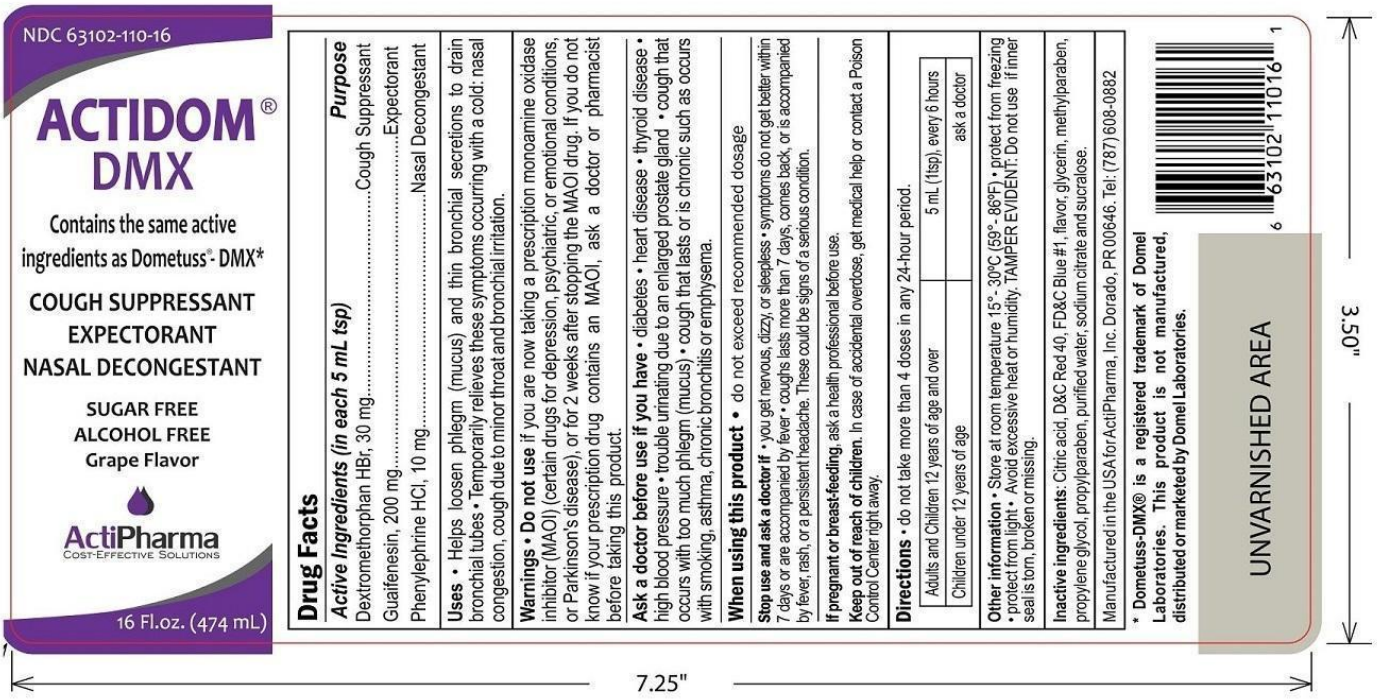
SUGAR FREE

ALCOHOL FREE

Grape Flavor

Packaging

FRONT PANEL



DRUG FACTS PANEL

Drug Facts

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UNVARNISHED AREA

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ACTIDOM DMX

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63102-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	purple (Clear)	**Score**	
Shape		**Size**	
Flavor	grape	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63102-110-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/13/2015	

Labeler - Actipharma, Inc (079340948)

Revised: 12/2018 Actipharma, Inc