ACTINEL DM- dextromethorphan hbr, guaifenesin, phenylephrine hcl 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.

ACTINEL® DM

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, USP.....20 mg

Guaifenesin, USP.....400 mg

Phenylephrine HCl, USP.....10 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

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, come 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.

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

Directions

- do not take more than 6 doses in any 24-hour period.

Adults and Children 12 years of age and over	5mL (1tsp), every 4 hours
Children under 12 years of age	ask a doctor

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. Pharmacist: Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP.

Inactive ingredients:

Artificial and natural flavors, citric acid, glycerin, menthol, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Contains the same active ingredients as Tusnel® DM*

SUGAR FREE

DYE FREE

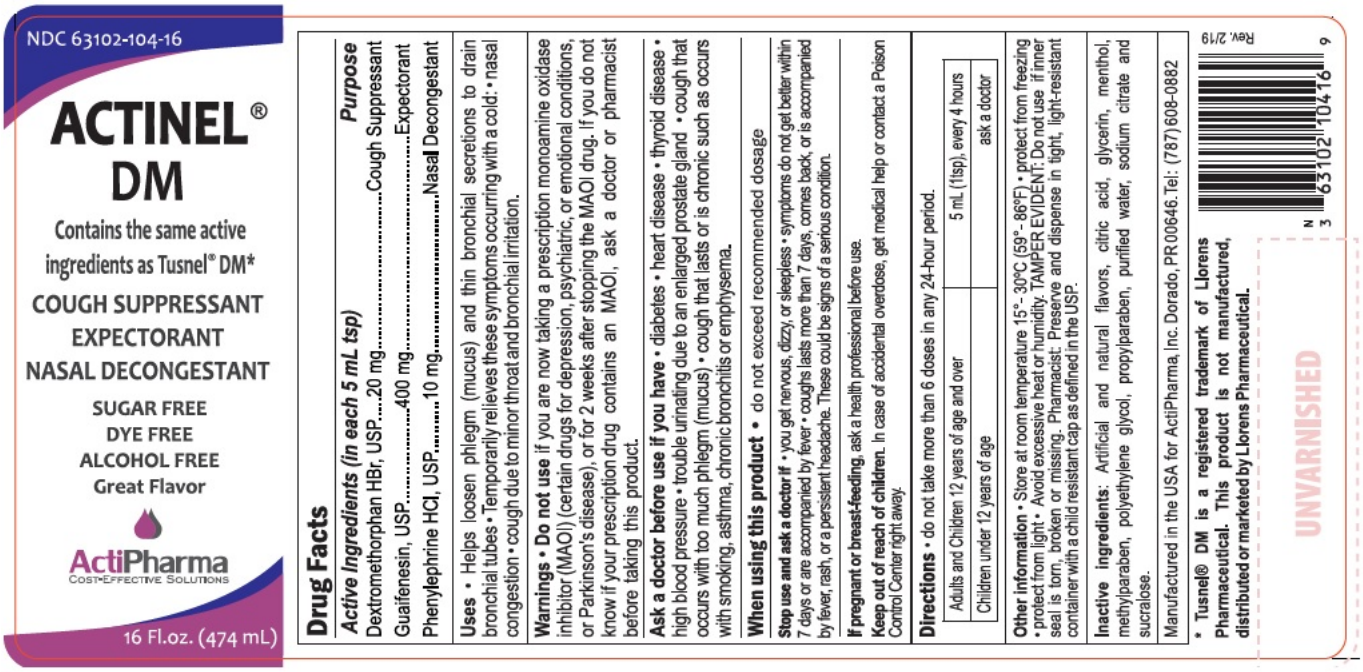
ALCOHOL FREE

Great Flavor

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

*** Tusnel® DM is a registered trademark of Llorens Pharmaceutical. This product is not manufactured, distributed or marketed by Llorens Pharmaceutical.**

Packaging



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ACTINEL DM

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63102-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-104-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/20/2019	

Labeler - Actipharma, Inc (079340948)

Revised: 5/2019 Actipharma, Inc