

ACTINEL DM- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution
ACTIPHARMA, LLC

ACTINEL® DM

Drug Facts

Active ingredients (in each 5 mL tsp)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purposes

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 • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland • cough accompanied by excessive phlegm (mucus) • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant.

When using this product do not exceed recommended dosage.

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • symptoms do not improve within 7 days or are accompanied by fever • cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or a persistent headache. A persistent cough may be a sign of a serious condition.

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

- take every 4 hours, or as directed by a doctor.

AGE	DOSE
adults and children 12 years of age and over	take 5mL (1tsp). Do not exceed 6 doses in 24 hours
Children under 12 years of age	ask a doctor

Other information

- tamper evident feature: Do not use if safety seal is torn, broken or missing.
- store at controlled room temperature 15° - 30°C (59° - 86°F).
- avoid excessive heat or humidity.

Inactive ingredients

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

Questions or comments?

+1-787-608-0882

You may also report serious side effects to this phone number.

call weekdays from 8AM to 4PM AST

Contains the same active ingredients as Tusnel® DM*

- Alcohol FREE • Dye FREE
- Sugar FREE • Great Flavor

Manufactured in USA with imported ingredients for ActiPharma. San Juan, PR 00917.
www.actipharma.net.

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

Packaging

NDC 63102-104-16

ACTINEL[®] DM

Contains the same active ingredients as Tusnel[®] DM*

**Dextromethorphan HBr
COUGH SUPPRESSANT
Guaifenesin
EXPECTORANT
Phenylephrine HCl
NASAL DECONGESTANT**

- Alcohol FREE ■ Dye FREE
- Sugar FREE ■ Great Flavor



16 fl oz (473 mL)

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Drug Facts (continued)

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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 Drug	M012	05/20/2019	

Labeler - ACTIPHARMA, LLC (079340948)

Revised: 6/2024

ACTIPHARMA, LLC