

**ACTINEL PEDIATRIC- dextromethorphan hbr, guaifenesin, pseudoephedrine
hcl solution
ACTIPHARMA, LLC**

ACTINEL® Pediatric

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 5 mg
Guaifenesin, 50 mg
Pseudoephedrine HCl, 15 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 in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

• heart disease • high blood pressure • thyroid disease • diabetes • cough that occurs with too much phlegm (mucus) • a persistent or chronic cough such as occurs with asthma

Ask a doctor or pharmacist before use if your child is taking any other oral nasal decongestant or stimulant.

When using this product do not use more than directed.

Stop use and ask a doctor if child

• gets nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever • cough lasts more than 7 days, comes back, or is accompanied

by fever, rash, or 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 overdose, get medical help or contact a Poison Control Center right away.

Directions

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

AGE	DOSE
Children 6 to under 12 years of age	Take 2 teaspoonfuls (10 mL) every 4-6 hours
Children 2 to under 6 years of age	Take 1 teaspoonful (5 mL) every 4-6 hours
Children under 2 years of age	Ask a doctor

Other information

- Tamper Evident Feature: Do not use if inner seal is torn, cut, or opened
- Store at controlled room temperature 15°- 30°C (59° -86°F)
- Avoid excessive heat or humidity.

Inactive ingredients

Citric Acid, Flavor, Methylparaben, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose

Questions or comments?

call weekdays from 8AM to 4PM AST at **1.787.608.0882**

Contains the same active ingredients as Tusnel® Pediatric*

SUGAR FREE

DYE FREE

ALCOHOL FREE

SACCHARIN FREE

COMMITTED TO HEALTH AND WELL-BEING

WWW.ACTIPHARMA.NET

Manufactured in USA with imported ingredients for ActiPharma, Inc.
San Juan, PR 00917.

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

Packaging

NDC 63102-102-16

ACTINEL®

Pediatric

Contains the same active ingredients as Tusnel® Pediatric*

**COUGH SUPPRESSANT
EXPECTORANT
NASAL DECONGESTANT**

SUGAR FREE
DYE FREE
ALCOHOL FREE
SACCHARIN FREE



16 Fl.oz. (473 mL)

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Drug Facts (continued)

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ACTINEL PEDIATRIC

dextromethorphan hbr,guaifenesin,pseudoephedrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-102-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/24/2014	

Labeler - ACTIPHARMA, LLC (079340948)