ACTINEL- dextromethorphan hbr,guaifenesin,pseudoephedrine 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

Drug Facts

Active Ingredients (in each 5mL tsp)

Dextromethorphan HBr, 15mg

Guaifenesin, 200 mg

Pseudoephedrine HCl, 30 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses:

temporarily:
• relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies
• relieves sinus congestion and pressure, help decongest sinus openings and passages
• restores freer breathing through the nose
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
• suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

Warnings:

• A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
• **Do not exceed recommended dosage.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.

Do not:
• take this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
• 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 child's… prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
• take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

Stop use and ask a doctor if:

• symptoms do not improve within 7 days or are accompanied by fever

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. Prompt medical attention is critical for adults as well as for children even if you do not notice any sign or symptoms.

Directions:

• Adults and children 12 years of age and over: Take 1 to 2 teaspoonfuls every 6 hours if needed, not to exceed 8 teaspoonfuls in 24 hours, or as directed by a doctor.
• Children 6-12 years, Take ½ to 1 teaspoonful every 6 hours if needed, do not exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor.
• Children under 6 years of age: consult a doctor

Other information

• Tamper Evident: Do not use if inner seal is torn, cut, or opened.

• Store at room temperature 15°- 30°C (59° - 86°F)

• Avoid excessive heat or humidity.

Inactive ingredients:

citric acid, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose

NEW FORMULA

Contains the same active ingredients as Tusnel®*

Dextromethorphan HBr

COUGH SUPPRESSANT

Guaifenesin

EXPECTORANT

Pseudoephedrine HCL

NASAL DECONGESTANT

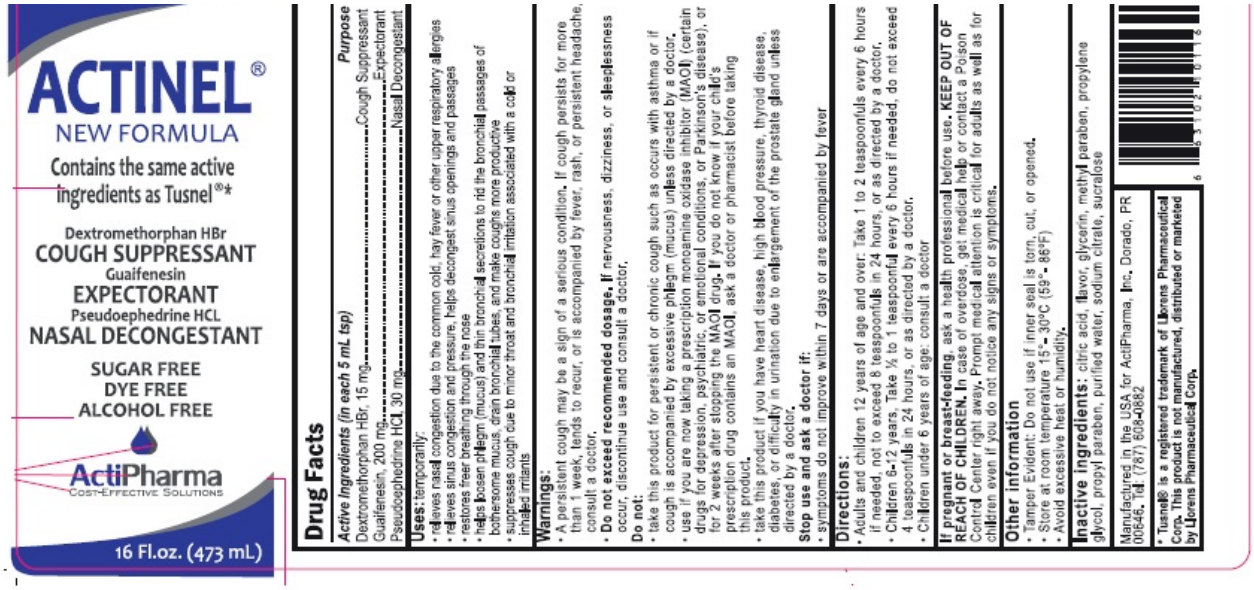
SUGAR FREE
DYE FREE
ALCOHOL FREE

COST –EFFECTIVE SOLUTIONS

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

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

Packaging



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ACTINEL

dextromethorphan hbr,guaifenesin,pseudoephedrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63102-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63102-101-16	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 final	part341	09/24/2014	

Labeler - Actipharma, Inc (079340948)

Revised: 12/2018 Actipharma, Inc