ALTIPRES PEDIATRIC- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Alternative Pharmacal Corporation

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.

Drug Facts

Active Ingredients (in each 5 mL tsp.) **Purpose**

Dextromethorphan HBr ..... 5 mg ..... Cough Suppressant

Guaifenesin ..... 75 mg ..... Expectorant

Phenylephrine HCl ..... 2.5 mg ..... Nasal Decongestant

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Warnings

Ask a doctor before use if your child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to the enlargement of the prostate gland
- a cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic as occurs with smoking, asthma, chronic bronchitis or emphysema

When using this product, do not exceed recommended dosage

Stop use and ask doctor if

- your 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

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 taking this product -Do not use- in a child under 2 years of age.

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.

Indications

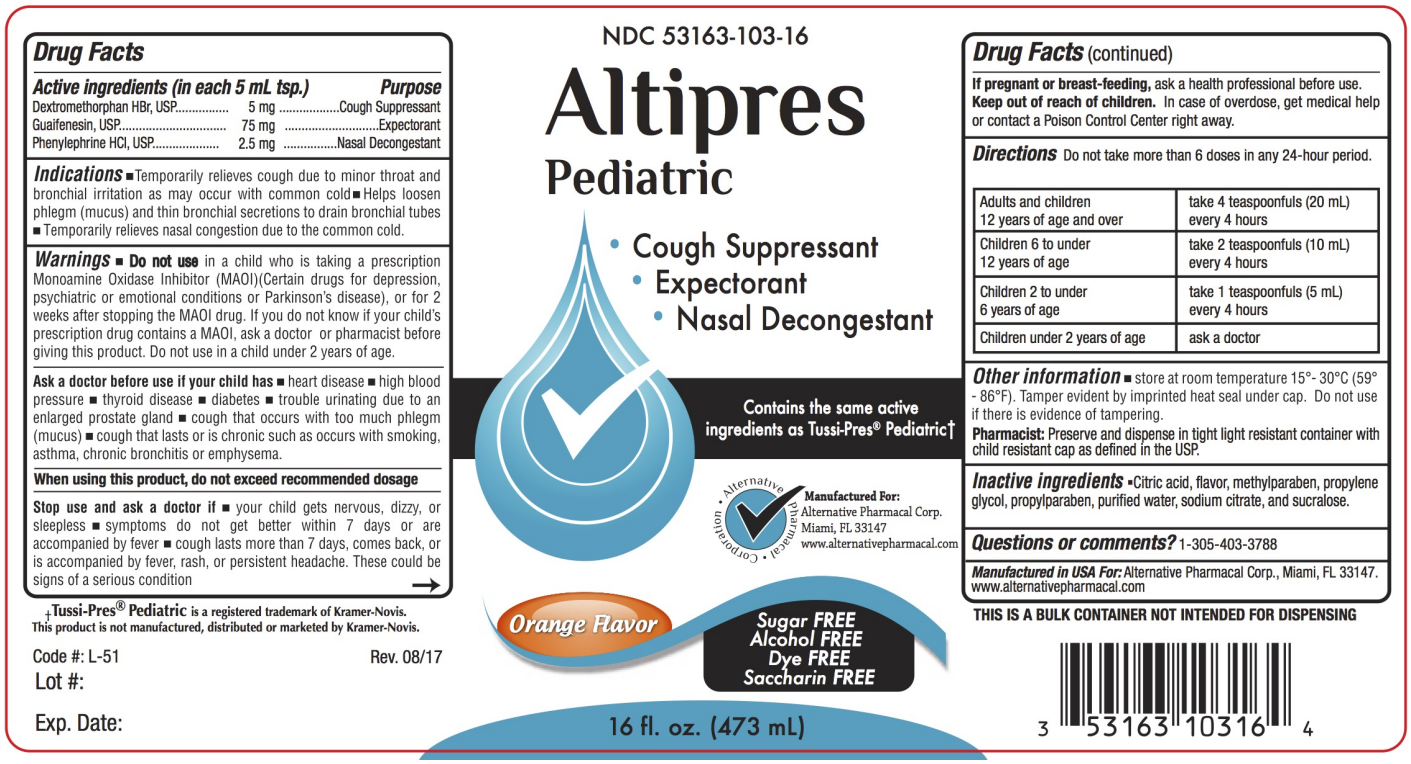
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves nasal congestion due to the common cold

Directions Do not exceed more than 6 doses in any 24-hour period

adults and children 12 years of age and over	take 4 teaspoonfuls (20 mL) every 4 hours
children 6 to under 12 years of age	take 2 teaspoonful (10 mL) every 4 hours
children 2 years to under 6 years of age	take 1 teaspoonful (5 mL) every 4 hours
children under 2 years of age	ask a doctor

Inactive ingredients citric acid, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sucralose

Questions or comments? 1-305-403-3788



ALTIPRES PEDIATRIC

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53163-103
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	75 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

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

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	ORANGE (Orange Flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53163-103-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2013	

Labeler - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020 Alternative Pharmacal Corporation