#### ALTIPRES-B- brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride 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.

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## **Drug Facts**

Active Ingredients (in each 5 mL tsp)	Purpose		
Brompheniramine maleate 4 mg	Antihistamine		
Dextromethorphan HBr 20 mg	Cough Suppressant		
Phenylephrine HCl 10 mg	Nasal Decongestant		

#### Purpose

**OAntihistamine** 

**Cough Suppressant** 

Nasal Decongestant

## Uses

- temporarily relieves symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- itchy nose or throat
- runny nose
- itchy, water eyes
- nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

## 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. Do not use on a child under 2 years of age.

# Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- glaucoma
- diabetes
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

# Ask a doctor or a pharmacist before

- giving this product to children who are taking sedatives or tranquilizers
- if you are taking sedatives or tranquilizers

Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor.

# When using this product

#### • do not use more than directed

- may cause drowsiness
- avoid alcoholic drink
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

## Stop use and ask a doctor if

- you get nervous, dizzy or sleeplessness
- 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.

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

**If pregnant or breast-feeding,** ask a health professional before use.

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

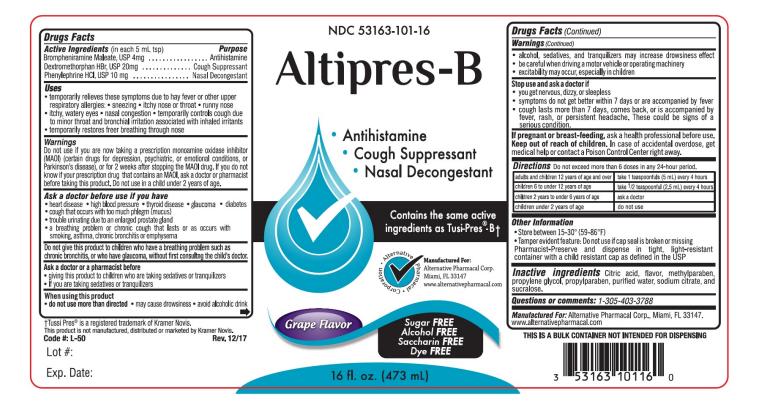
adults and children 12 years of age and over	take 1 teaspoonfuls (5 mL) every 4 hours
children 6 to under 12 years of age	take 1/2 teaspoonfuls (2.5mL) every 4 hours
children 2 years to under 6 years of age	ask a doctor
children under 2 years of age	do not use

**Inactive Ingredients** citric acid, flavor, methylparaben, propylene glycol, propylparaben, pruified water, sodium citrate, and sucralose

Questions or comments: 1-305-403-3788

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## **ALTIPRES-B**

brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53163-101
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	Strength
<b>BRO MPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)PHENYLEPHRINE HYDRO CHLO RIDE		10 mg in 5 mL

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

P	roduct Characte	ristics			
C	olor		Score		
S	hape		Size		
F	lavor	GRAPE (grape flavor)	Imprint Code		
C	ontains				
P	ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing Er	nd Date
1	NDC:53163-101-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/0 1/20 12		
Marketing Information					
ľ	Aarketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing En	d Date
0	TC monograph final	part341	11/0 1/20 12		

# Labeler - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020

Alternative Pharmacal Corporation