# ALTICOTRON- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops 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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Active Ingredients (in each 1 mL)		Purpose	
Dextromethorphan HBr	5 mg	Cough Suppressant	
Guaifenesin	. 100 mg	Expectorant	
Phenylephrine HCl	2.5 mg	Nasal Decongestant	

Cough Suppressant

**Expectorant** 

Nasal Decongestant

#### Uses

- non-narcotic cough suppreassant which temporarily calms due to minor throat and bronchial irritation as may occur with common cold
- helps decongest sinus openings and passages; temporarily relieves sinus openings and passages; temporarily relieves sinus congestion and pressur
- helps lossen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves nasal congestion due to the common cold
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

# **Warnings**

Date persistant cough may be 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 USE

If a child 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 that contains MAOI; ask your doctor or pharmacist before taking this product.

# **Ask a doctor before use if the child has:**

- Heart disease
- High blood pressure
- Thyroid deases
- Diabetes
- Cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or where cough is accompanied by excessive phlegm (mucus)

# When using this product do not exceed recommended dosage.

# Stop use and ask a doctor before use 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.

**IIf pregnant or breast-feeding,** <code>Bask</code> a health profession before use.

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

### Directions

- Do not use more than 6 doses in any 24 hour period
- Repeat every 4 hours
- Measure with dosage device provided. Do not use with any other device

Children 6 years to under 12 years of age	2 ml
Children 2 years to under 6 years of age	Ask a doctor
Children under 2 years of age	Ask a doctor

# **Other Information**

□Store at room temperature 15□0□ - 30□0□C (59□0□-86□0□F)

**Tamper Evident Feature:** Do not use if seal is torn, broken or missing. Avoid excessive heat or humidity.

# **□Inactiveingredients □□**

citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, and sucralose

**Questions or comments? 11-786-507-1566** 

#### NDC 53163-107-02 Drug Facts Active ingredients (in each 1 mL) Dextromethorphan HBr,...... 5 mg Purpose Alticotron Cough Suppressant Uses = non-narcotic cough suppressant which temporarily calms due to minor throat and bronchial irritation as may occur with common cold = helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure = helps dosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive = temporarily relieves nasal congestion due to the common cold = helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure = which is the common cold = helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure **PED Drops** Cough Suppressant Expectorant Nasal Decongestant 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 use in a child who is taking a Contains the same active ingredients as Broncotron® PED Drops 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 the child has " heart disease " high blood pressure " Manufactured For thyroid disease . diabetes . cough that lasts or is chronic such as occurs with asthma Miami, FL 33166 chronic bronchitis, or where cough is accompanied by excessive phlegm (mucus) When using this product do not exceed recommended dosage. Stop use and ask a doctor if • your child gets nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever • cough last Grape Flavor Sugar FREE Alcohol FREE Dye FREE Gluten FREE

Drug Facts (continued)

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

Directions: - Do not use more than 6 doses in any 24 hour period - Repeat every 4 hours - Measure with the dosage device provided. Do not use with any other device.

Age	Dose	
Children 6 to under 12 years of age	2 mL	
Children 2 to under 6 years of age	Ask a doctor	
Children under 2 years of age	Ask a doctor	

Other information - Tamper Evident Feature: Do not use if cap seal is torn, broken or missing. = Store at room temperature 15-30°C (59-86°F Avoid excessive heat and humidity

Inactive ingredients: Citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or comments? 1-786-507-1566

Manufactured For: Alternative Pharmacal Corp., Miami, FL 33166. www.alternativepharmacal.com



Exp. Date:

Rev. 9/14

2 fl. oz. (60 mL)

# ALTICOTRON

more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

#### **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:53163-107 ORAL Route of Administration

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 1 mL
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDRO CHLO RIDE	2.5 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:53163-107-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
N	Iarketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
O'	ΓC monograph final	part341	0 3/0 1/20 15	

# Labeler - Alternative Pharmacal Corporation (078528214)

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