

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.

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 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 openings and passages; temporarily relieves sinus congestion and pressure
- helps loosen 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

A persistent 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 diseases
- 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.

ⓂIf pregnant or breast-feeding, Ⓜask a health profession 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 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 15⁰⁰ - 30⁰⁰ⓂC (59⁰⁰-86⁰⁰ⓂF)

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

ⓂInactive ingredients

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

ⓂQuestions or comments? Ⓜ1-786-507-1566

Drug Facts

Active ingredients (in each 1 mL)	Purpose
Dextromethorphan HBr,..... 5 mg	Cough Suppressant
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Phenylephrine HCl,..... 2.5 mg	Nasal Decongestant

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Ask a doctor before use if the child has ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ cough that lasts or is chronic such as occurs with 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 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.

Lot #:

Rev. 9/14

Exp. Date:

NDC 53163-107-02

Alticotron

PED Drops



- Cough Suppressant
- Expectorant
- Nasal Decongestant

Contains the same active ingredients as Broncotron® PED Drops



Manufactured For:
Alternative Pharmaceutical Corp.
Miami, FL 33166
www.alternativepharmaceutical.com

Grape Flavor

Sugar FREE
Alcohol FREE
Dye FREE Gluten FREE

2 fl. oz. (60 mL)

Drug Facts (continued)

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

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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

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53163-107
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 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg

GOAIPENESIN (UNII: 493W7491VQ) (GOAIPENESIN - UNII:493W7491VQ)	GOAIPENESIN	in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53163-107-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2015	

Labeler - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020

Alternative Pharmacal Corporation