

ALTIDESP- 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..... 50 mg.....	Expectorant
Phenylephrine HCl..... 2.5 mg.....	Nasal Decongestant

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold.

Warnings

Do not exceed recommended dosage

If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor. If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

Do not use 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.

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 two 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.

Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.

Stop use and ask a doctor before use if:

- A persistent cough may be a sign of a serious condition
- If cough persists for more than one week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

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.

Directions

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

Age	Dose
Children 2 years to under 6 years of age	1 mL every 4 hours
Children under 2 years of age	consult 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.

Inactive ingredients

calcium saccharin, citric acid, flavors, glycerin, methylparaben, propylene glycol, propylparaben, purified water and sodium citrate

Questions or comments? 1-786-507-1566

Drug Facts

Active Ingredients (in each 1mL)

Ingredient	Amount	Purpose
Dextromethorphan HBr	5mg	Cough Suppressant
Guaifenesin	50mg	Expectorant
Phenylephrine HCl	2.5mg	Nasal Decongestant

Uses: • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive • temporarily relieves nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold.

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Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.

Stop use and ask a doctor: • A persistent cough may be a sign of a serious condition; • if cough persists for more than one week, tend to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

†Despec®EDA Drops is a registered trademark of International Ethical Labs. This product is not manufactured, distributed or marketed by International Ethical Labs.

NDC: 53163-108-01

Altidesp EDA DROPS

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Contains the same active ingredients as Despec[®]† EDA Drops

Cherry Flavor

**Sugar FREE
Alcohol FREE
Dye FREE**

1 fl. oz. (30 mL)

Drug Facts (cont.)

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

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

Age	Dose
children 2 to under 6 years of age	1 mL every 4 hours
children under 2 years of age	consult a doctor

Other information: • Store at room temperature 15°-30°C (59-86°F)
Tamper evident: Do not use if there is evidence of tampering.

Inactive ingredients: Calcium saccharin, citric acid, flavors, glycerin, methylparaben, propylene glycol, propylparaben, purified water and sodium citrate.

Questions or comments? 1-786-507-1566

NON VARNISH



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ALTIDESP

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53163-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN CALCIUM (UNII: 5101OP7P2I)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53163-108-01	30 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