

**ALTIDESP- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/
drops**

Alternative Pharmacal Corporation

Alt- AltidespEDADr 108

| 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 heachache, consult a doctor.

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
- 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 15⁰ - 30⁰ C (59⁰-86⁰ 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)

| | |
|--|----------------|
| Dextromethorphan HBr.....5mg.....Cough Suppressant | Purpose |
| 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.

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 Monoamineoxidase 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:** • 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

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

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 |
|---|----------------------------------|-------------------|
| 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: 059QF0KO0R) | |
| 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 Drug | M012 | 03/01/2015 | |

Labeler - Alternative Pharmacal Corporation (078528214)