**ENDAL- triprolidine hcl, dextromethorphan hbr liquid**
**Poly Pharmaceuticals, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Endal**

## Active Ingredient

Triprolidine HCl, Dextromethorphan HBr

## Purpose

Antihistimine, Antitussive

## Uses

Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation

## Warnings

Do not exceed recommended dosage.

## Do not use this product

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.

## Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to the enlargement of the prostate gland
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm
- a chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- heart disease

- high blood pressure
- thyroid disease
- diabetes

**Ask a doctor or pharmacist before use**

if you are taking sedatives or tranquilizers.

**When using this product**

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- may cause or aggravate constipation
- alcohol, sedatives, and tranquilizers may increase drowsiness effect

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache.

These could be signs of a serious
- new symptoms occur

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of the reach of children**

. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

| AGE | DOSE |
|---|---|
| Adults and children over 12 years of age | 2 teaspoonfuls (10 mL) every 4 to 6 hours, over 12 years not to exceed 8 teaspoonfuls in of age: 24 hours, or as directed by a doctor. |
| Children 6 to under 12 years of age | 1 teaspoonful (5 mL) every 4 to 6 hours, 12 years of age: not to exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor. |
| Children under 6 years of age | Consult a doctor. |

**Other Information**

Store at 59° - 86°F (15° - 30°C)

## Inactive Ingredients

Citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution.

## Questions? Comments?

Serious side effects associated with use of this product may be reported to this number. Call 1-800-882-1041 Mon - Fri (8 a.m. to 5 p.m. CST)

## Package Label

NDC 50991-136-16

**ENDAL**

**LIQUID**

Antihistamine • Antitussive
Alcohol Free • Dye Free
Sugar Free • Gluten Free

Each 5 mL (1 teaspoonful) contains:
Triprolidine HCl . . . . . 1.25 mg
Dextromethorphan HBr . . . . . 10 mg

Grape Flavor

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.
Dispense in a tight, light-resistant container with a child-resistant cap. This bottle is not to be dispensed to consumer.

Distributed by:
Poly Pharmaceuticals
Huntsville, AL 35763

N 3 50991 13616 6

16 fl oz. (473 mL)

**Drug Facts**

**Active ingredients (in each 5 mL teaspoonful)** — **Purpose**
Triprolidine HCl 1.25 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Antitussive

**Uses** temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:
- runny nose ■ sneezing ■ itching of the nose or throat
- itchy, watery eyes ■ cough due to minor throat and bronchial irritation

**Warnings**

**Do not exceed recommended dosage.**

**Do not use this product**
- 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.

**Ask a doctor before use if you have**
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to the enlargement of the prostate gland
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm
- a chronic pulmonary disease or shortness of breath, or children who are taking other drugs ■ heart disease
- high blood pressure ■ thyroid disease ■ diabetes

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

**When using this product**
- excitability may occur, especially in children
- may cause marked drowsiness ■ avoid alcoholic drinks
- may cause or aggravate constipation
- alcohol, sedatives, and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery

**Drug Facts** (continued)

**Stop use and ask a doctor if**
- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms occur

**If pregnant or breast-feeding, ask a health professional before use.**
**Keep out of the reach of children.**
**In case of overdose, get medical help or contact a Poison Control Center right away.**

**Directions**

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**Other information**
Store at 59° - 86°F (15° - 30°C)

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Citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution.

**Questions? Comments?**
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Mon - Fri (8 a.m. to 5 p.m. CST)

Iss. 3/23

# ENDAL

triprolidine hcl, dextromethorphan hbr liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50991-136 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **TRIPROLIDINE HYDROCHLORIDE** (UNII: YAN7R5L890) (TRIPROLIDINE - | TRIPROLIDINE | 1.25 mg |

| | | |
|---|---|---|
| UNII:2L8T9S52QM) | HYDROCHLORIDE | in 5 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SORBITOL SOLUTION** (UNII: 8KW3E207O2) | |
| **CITRIC ACID ACETATE** (UNII: DSO12WL7AU) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:50991-136-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/22/2023 | |
| **2** | NDC:50991-136-15 | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/22/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 05/22/2023 | |

## Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.