

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

Endal

Active Ingredient

Tripolidine 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) Triprolidine HCl 1.25 mg Antihistamine Dextromethorphan HBr 10 mg Antitussive	Purpose
Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies: <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 Do not exceed recommended dosage.	
AGE	DOSE
Adults and children over 12 years of age:	2 teaspoonfuls (10 mL) every 4 to 6 hours, not to exceed 8 teaspoonfuls in 24 hours, or as directed by a doctor.
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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)	

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 - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg 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
OTC Monograph Drug	M012	05/22/2023	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 7/2024

Poly Pharmaceuticals, Inc.