TRICODE AR- chlorpheniramine maleate, codeine phosphate, pseudoephedrine hydrochloride liquid

Respa Pharmaceuticals, Inc.

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.

Tricode AR

Drug Facts
Active ingredients
(in each 5 mL teaspoonful)
Chlorpheniramine Maleate 2 mg
Codeine Phosphate* 8 mg
*WARNING: May be habit forming
Pseudoephedrine Hydrochloride 30 mg

Purpose

Antihistamine Antitussive (Cough Suppressant) Nasal Decongestant

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
- nasal congestion
- reduces swelling of nasal passages

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
- trouble urinating due to an enlarged 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 (mucus)

- 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- may cause or aggravate constipation
- nervousness, dizziness, or sleeplessness occur
- 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.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 4 to 6 hours, not to exceed 8 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 4 teaspoonfuls in a 24 hour period

Children under	Consult a doctor.
6 years of age:	

A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

Other information

Store at 15°- 30°C (59°- 86°F)

Inactive ingredients

Berry Vanilla Flavor, Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

Call (630) 543-3333

Rx Only

 \mathbf{CV}

Manufactured for:

RESPA® PHARMACEUTICALS, INC.

Addison, IL 60101

Product Packaging

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 60575-313-16

Tricode AR®

Antihis tamine · Cough Suppress ant Nas al Decongestant

Each 5 mL (one teaspoonful) for oral administration contains:

Chlorpheniramine Maleate2	mg
Codeine Phosphate*8 r	ng
*(Warning: May be habit-forming)	
Pseudoephedrine HCl30	mg

Dye Free / Sugar Free Alcohol Free / Gluten Free

Berry Vanilla Flavor

Rx Only

RESPA® PHARMACEUTICALS, INC. Addison, IL 60101

16 fl oz. (473 mL)

SEE ATTACHED PRODUCT INSERT FOR COMPLETE DOSING INFORMATION.

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

THIS BOTTLE IS NOT TO BE DISPENSED TO THE CONSUMER.

Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Store at controlled room temperature, 15°- 30°C (59°- 86°F).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for: Respa Pharmaceuticals Addision, IL 60101

Rx Only

Rev. 08/11

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Manufactured for: Respa Pharmaceuticals Addison, IL 60101

Rx Only

Rev. 08/11



NDC 60575-313-16

Tricode® AR

Antihistamine • Cough Suppressant Nasal Decongestant

Dye Free / Sugar Free Alcohol Free / Gluten Free

Berry Vanilla Flavor
Rx Only



Addison, IL 60101

16 fl oz. (473 mL)

Drug Facts

Lift Here

Active ingredients Purpose (in each 5 mL teaspoonful)

Chiorpheniramine
Maleate 2 mg Antihistamine
Codeline Antitussive
Phosphate* 8 mg(Cough Suppressant)
*WARNING: May be habit forming
Pseudoephedrine
Hydrochioride 30 mg ... Nasal Decongestant

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

=runny nose = sneezing = fiching of the nose or throat = lichly, watery eyes

=cough due to minor throat and bronchial irritation = nasal congestion

■reduces swelling of nasal passages

Warnings

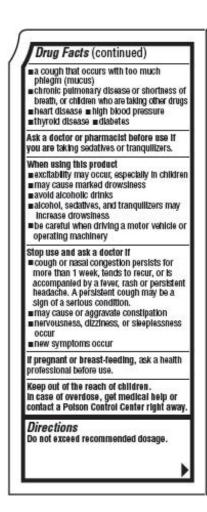
Do not exceed recommended dosage.

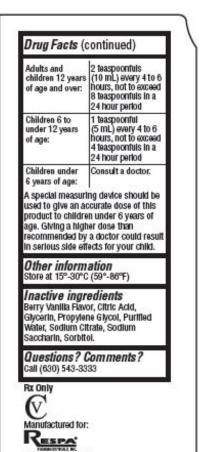
Do not use this product

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Ask a doctor before use if you have ma breathing problem such as emphysema or chronic bronchitis mglaucoma

- trouble urinating due to an enlarged prostate gland
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema





TRICODE AR

chlorpheniramine maleate, codeine phosphate, pseudoephedrine hydrochloride liquid

Addison, IL 60101

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60575-313
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	2 mg in 5 mL	
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	8 mg in 5 mL	
Pseudoephedrine Hydrochloride (UNII: 6V9 V2RYJ8N) (Pseudoephedrine - UNII:7CUC9 DDI9F)	Pseudo ephedrine Hydro chlo ride	30 mg in 5 mL	

Inactive Ingredients

Ingredient Name	Strength	
Citric Acid (UNII: 2968 PHW8 QP)		
Glycerin (UNII: PDC6A3C0OX)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Water (UNII: 059QF0KO0R)		
Sodium Citrate (UNII: 1Q73Q2JULR)		
Saccharin Sodium (UNII: SB8ZUX40TY)		
Sorbitol (UNII: 506T60A25R)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY, VANILLA	Imprint Code	
Contains			

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:60575-313-16	473 mL in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/20/2011		

Labeler - Respa Pharmaceuticals, Inc. (883901019)

Revised: 9/2011 Respa Pharmaceuticals, Inc.