

TRICODE GF- codeine phosphate, guaifenesin, 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 GF

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Codeine Phosphate* 8 mg

***(Warning: May be habit-forming)**

Guaifenesin 200 mg

Pseudoephedrine Hydrochloride 30 mg

Purpose

Antitussive (Cough Suppressant)

Expectorant

Nasal Decongestant

Uses

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

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- 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 cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis 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

- trouble urinating due to an enlarged prostate gland

When using this product

- May cause or aggravate constipation

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.
- 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 accidental 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 6 years of age	Consult a doctor.

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

Bitter Mask, Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

Call (630) 543-3333

Rx Only

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 60575-414-16

Tricode® GF

**Cough Suppressant•Expectorant
Nasal Decongestant**

CV

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

Codeine Phosphate*.....8 mg

*(Warning: May be habit-forming)

Guaifenesin.....200 mg

Pseudoephedrine HCl.....30 mg

Dye Free / Sugar Free

Alcohol Free / Gluten Free

Grape 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
Addison, IL 60101

Rx Only

Rev. 08/11

<p>SEE ATTACHED PRODUCT INSERT FOR COMPLETE DOSING INFORMATION.</p> <p>Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.</p> <p>THIS BOTTLE IS NOT TO BE DISPENSED TO THE CONSUMER.</p> <p>Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.</p> <p>Store at controlled room temperature, 15°-30°C (59°-86°F).</p> <p>KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.</p> <p>Manufactured for: Respa Pharmaceuticals Addison, IL 60101</p> <p>Rx Only</p> <p>Rev. 08/11</p> 	<p>NDC 60575-414-16</p> <hr/> <p>Tricode® GF</p> <p>Cough Suppressant • Expectorant Nasal Decongestant</p> <hr/>  <p>Each 5 mL (one teaspoonful) for oral administration contains: Codeine Phosphate* 8 mg *(Warning: May be habit-forming) Guaifenesin 200 mg Pseudoephedrine HCl 30 mg</p> <p>Dye Free / Sugar Free Alcohol Free / Gluten Free Grape Flavor Rx Only</p> <p>RESPA® PHARMACEUTICALS, INC. Addison, IL 60101</p> <p>16 fl oz. (473 mL)</p>	<p>Drug Facts Lift Here ▶</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td colspan="2">(in each 5 mL teaspoonful)</td></tr><tr><td>Codeine</td><td>Antitussive</td></tr><tr><td>Phosphate* 8 mg</td><td>(Cough Suppressant)</td></tr><tr><td colspan="2">*(Warning: May be habit-forming)</td></tr><tr><td>Guaifenesin 200 mg</td><td>Expectorant</td></tr><tr><td>Pseudoephedrine</td><td></td></tr><tr><td>Hydrochloride 30 mg</td><td>Nasal Decongestant</td></tr></tbody></table> <p>Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:</p> <ul style="list-style-type: none">■ cough due to minor throat and bronchial irritation■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive■ nasal congestion■ reduces swelling of nasal passages <p>Warnings</p> <p>Do not exceed recommended dosage.</p> <p>Do not use this product</p> <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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">■ a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis 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	Active ingredients	Purpose	(in each 5 mL teaspoonful)		Codeine	Antitussive	Phosphate* 8 mg	(Cough Suppressant)	*(Warning: May be habit-forming)		Guaifenesin 200 mg	Expectorant	Pseudoephedrine		Hydrochloride 30 mg	Nasal Decongestant
Active ingredients	Purpose																	
(in each 5 mL teaspoonful)																		
Codeine	Antitussive																	
Phosphate* 8 mg	(Cough Suppressant)																	
*(Warning: May be habit-forming)																		
Guaifenesin 200 mg	Expectorant																	
Pseudoephedrine																		
Hydrochloride 30 mg	Nasal Decongestant																	

Drug Facts (continued)

- trouble urinating due to an enlarged prostate gland

When using this product

- May cause or aggravate constipation

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.

- 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 6 years of age:	Consult a doctor.
--------------------------------	-------------------

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.

Drug Facts (continued)**Other information**

Store at 15°-30°C (59°-86°F)

Inactive ingredients

Bitter Mask, Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

Call (630) 543-3333

Rx Only



Manufactured for:



Addison, IL 60101

TRICODE GF

codeine phosphate, guaifenesin, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60575-414
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	8 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid (UNII: 2968PHW8QP)	

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	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60575-414-16	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)