NINJACOF-XG - codeine phosphate liquid Centurion Labs, LLC

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.

Ninjacof-XG

Active ingredients (in each 5 mL)	Purpose
Codeine Phosphate*8 mg	Antitussive (Cough Suppressant)
Guaifenesin 200 mg	Expectorant

^{*} Warning: May be habit forming

Uses Temporarily relieves:

- 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

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucas)
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs

Stop use and ask a doctor if

- cough 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
- product may cause or aggravate constipation

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 Take this medication with a full glass of water after each dose to help loosen mucus in the lungs

Adults and children	2 teaspoonfuls (10mL) every
12 years of age	4 hours, not to exceed
and over:	12 teasoonfuls in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours
*Children under 6 years of age:	Consult a doctor.

^{*} Giving a higher dose than recommended by a doctor could result in serious side effects.

Other Information

Store at 15° - 30°C (59° - 86°F).

Inactive Ingredients

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

Questions? Comments?

To report a serious adverse event or obtain product information, contact 1-866-959-4880

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

23359-040-16

Ninjacof-XG

Cotton Candy

Flavor

CENTURION

16 fl oz (473 mL)

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

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:

Centurion Labs, LLC Birmingham, AL 35243

Drug Facts

Active ingredients (in each 5 ml.) Purpose

Codeine Phosphate* 8 mg.... Antitussive (Cough Suppressant)

*(Warning: May be habit-forming) Guaifenesin 200 mg...... Expectoran

Uses Temporarily relieves:

- cough due to minor throat and bronchial irritation
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- a cough that occurs with too much phiegm (mucas)
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- new symptoms occur
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Ninjacof-XG

Antitussive • Expectorant

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

(Warning: Maybe habit forming)

Alcohol Free . Dye Free . Sugar Free

Cotton Candy Flavor



16 fl oz (473 mL)

Drug Facts (continued)

Directions Take this medication with a full glass of water after each dose to help loosen mucus in

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

*Giving a higher dose than recommended by a doctor could result in serious side effects.

Other Information Store at 15"-30"C (59" - 86"F).

Inactive Ingredients

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

Questions? Comments?
To report a serious adverse event or obtain product information, contact 1-866-959-4880

Tamper evident by foil seal under cap. Do not use if foil

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°-88°F)

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

Manufactured for: Centurion Labs, LLC Birmingham, AL 35243



NINJACOF-XG

codeine phosphate liquid

Product Information

Inactive Ingredients

HUMAN OTC DRUG NDC:23359-040 Product Type Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine Anhydrous - UNII:UX6OWY2V7J)	Codeine Phosphate	8 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL

Ingredient Name Strength Citric Acid Monohydrate (UNII: 2968PHW8QP) Glycerin (UNII: PDC6A3C0OX) Propylene Glycol (UNII: 6DC9Q167V3) Water (UNII: 059QF0KO0R)

Sodium Citrate (UNII: 1Q73Q2JULR) Saccharin Sodium (UNII: SB8ZUX40TY)

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:23359-040-16	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/20/2014	

Labeler - Centurion Labs, LLC (806756461)

Sorbitol (UNII: 506T60A25R)

Registrant - Centurion Labs, LLC (806756461)

Revised: 11/2014 Centurion Labs, LLC