

**NINJACOF- chlophedianol hcl and pyrilamine maleate solution**  
**Centurion Labs, LLC**

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**Ninjacof**

**OTC - ACTIVE INGREDIENT SECTION**

**Active ingredients (in each 5 ml) Purpose**

Chlophedianol HCl 12.5 mg ..... Antitussive  
Pyrilamine Maleate 12.5 mg ..... Antihistamine

**Purpose**

Antitussive

Antihistamine

**INDICATIONS & USAGE SECTION**

**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
- calms the cough control center and relieves coughing
- runny nose
- sneezing
- itching of the nose and throat
- itchy, watery eyes

**WARNINGS SECTION**

**WARNINGS**

**Do not exceed recommended dosage**

**DO NOT USE IF PRINTED SAFETY SEAL IS MISSING OR BROKEN**

- If you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions or Parkinsons 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, or emphysema
- A cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before us if you are:**

- Taking sedatives or tranquilizers
- If you have a breathing problem such as emphysema or chronic bronchitis
- If you have glaucoma

- If you have difficulty in urination due to enlargement of the prostate gland

## **OTC - WHEN USING SECTION**

### **When using this product**

- Excitability may occur, especially in children
- Marked drowsiness may occur
- Avoid alcoholic drinks
- Alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- Be careful when driving a motor vehicle or operating machinery

## **OTC - DO NOT USE SECTION**

### ***Stop use and ask a doctor if***

- Nervousness, dizziness, or sleeplessness occurs
- Symptoms do not improve within 7 days or are accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
- New symptoms occur

## **OTC - PREGNANCY OR BREAST FEEDING SECTION**

### ***If pregnant or breast-feeding***

Ask a health professional before use.

## **OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

### ***Keep out of reach of children.***

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

## **Dosage and Administration**

### ***Directions***

Do not exceed recommended dosage. Use calibrated measuring device for administering the drug to a child.

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Adults and children 12 years of age and over:	2 teaspoonfuls (10 ml) every 6 to 8 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 teaspoonful (5 ml) every 6 to 8 hours, not to exceed 3 teaspoonfuls in 24 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

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**Other Information** Store at 20° -25°C (68°-77°F); excursions permitted to 15°-30°C

(59° - 86°F). [See USP Controlled Room Temperature].

## INACTIVE INGREDIENT SECTION

**Inactive Ingredients** Citric Acid, Glycerin, Natural & Artificial Flavors, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sucralose

## OTC - QUESTIONS SECTION

### Questions? Comments?

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

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

23359-032-16

**Ninjacof**<sup>TM</sup>

Antitussive • Antihistamine

Each teaspoonful (5 mL) Contains:

Chlorphedianol HCl ..... 12.5 mg  
Pyrilamine Maleate ..... 12.5 mg

Alcohol Free • Dye Free • Sugar Free

Cotton Candy Flavor

CENTURION

16 fl oz (473 mL)

Manufactured for: Centurion Labs, LLC Birmingham, AL 35243 Rev. 2/2015

3 2335-9032-16 5

Drug Facts	
<b>Active Ingredients (in each 5 mL (1 tsp))</b>	<b>Purpose</b>
Chlorphedianol HCl 12.5 mg.....	Antitussive
Pyrilamine Maleate 12.5 mg.....	Antihistamine
<b>Uses</b> 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	
• Runny Nose	
• Sneezing	
• Itching of the nose or throat	
• Itchy, watery eyes	
<b>WARNINGS</b>	
Do not exceed recommended dosage	
DO NOT USE IF PRINTED SAFETY SEAL IS MISSING OR BROKEN	
Do not use this product	
• If you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions or Parkinson 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, or emphysema	
• A cough that occurs with too much phlegm (mucus)	
Ask doctor or pharmacist before use if you are	
• Taking sedatives or tranquilizers	
• If you have a breathing problem such as emphysema or chronic bronchitis	
• If you have glaucoma	
• If you have difficulty in urination due to enlargement of the prostate gland	
<b>When using this product</b>	
• Excitability may occur, especially in children	
• Marked drowsiness may occur	
• Avoid alcoholic drinks	
• Alcohol, sedatives, and tranquilizers may increase drowsiness	
• Be careful when driving a motor vehicle or operating machinery	

Drug Facts (continued)	
<b>Stop use and ask a doctor if</b>	
• Nervousness, dizziness, or sleeplessness occurs	
• Symptoms do not improve within 7 days or are accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.	
• New symptoms occur	
<b>If pregnant or breastfeeding</b>	
Ask a health professional before use	
<b>Keep out of reach of children.</b>	
In case of overdose, get medical help or contact a Poison Control Center right away	
<b>Directions</b>	
• Do not exceed recommended dosage	
Adults and children 12 years of age and over:	2 teaspoonfuls (10mL) every 6 to 8 hours not to exceed 8 teaspoonfuls in 24hr
Children 6 to under 12 years of age:	1 teaspoonful (5mL) every 6 to 8 hours not to exceed 4 teaspoonfuls in 24hr
Children under 6 years of age:	Consult a doctor
<b>Other Information</b>	
Store at 20° - 25°C (68°- 77°F); excursions permitted to 15°-30°C (59° - 86°F). (See USP Controlled Room Temperature)	
<b>Inactive Ingredients</b>	
Citric Acid, Glycerin, Natural & Artificial Flavors, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sucralose	
<b>Questions? Comments?</b>	
To report a serious adverse event or obtain product information, contact 1-866-959-4880	

23359-032-16

Ninjacof

Antitussive, Antihistamine

Each teaspoonful (5mL) Contains:

Chlorphedianol HCl.....12.5mg

Pyrilamine Maleate.....12.5mg

Alcohol Free Dye Free, Sugar Free

Cotton Candy Flavor

Centurion

16 fl oz (473 mL)

Manufactured for Centurion Labs, LLC Birmingham, AL 35243

Rev: 2/2015

EXP:

Lot:



23359-032-10

Ninjacof

Antitussive, Antihistamine

Each teaspoonful (5mL) Contains:

Chlophendianol HCl.....12.5mg

Pyrilamine Maleate.....12.5mg

Alcohol Free Dye Free, Sugar Free

Cotton Candy Flavor

Centurion

16 fl oz (473 mL)

Manufactured for Centurion Labs, LLC Birmingham, AL 35243

Rev: 2/2015

EXP:

Lot:

23359-032-04

**Ninjacof™**

Antitussive • Antihistamine

Each teaspoonful (5 mL) Contains:  
 Chlorpheniramine HCl ..... 12.5 mg  
 Pyrilamine Maleate ..... 12.5 mg

Alcohol Free • Dye Free • Sugar Free

**Cotton Candy Flavor**

**CENTURION**  
4 fl oz (120 mL)

Manufactured for: Centurion Labs, LLC Birmingham, AL 35243  
 Rev: 2/2015

3 23359-032-04 2

Drug Facts	
<b>Active Ingredients (in each 5 mL (1 tsp))</b>	<b>Purpose</b>
Chlorpheniramine HCl 12.5 mg	Antitussive
Pyrilamine Maleate 12.5 mg	Antihistamine
<b>Uses</b> Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies.	
<ul style="list-style-type: none"> <li>• Cough due to minor throat and bronchial irritation</li> <li>• Runny Nose</li> <li>• Sneezing</li> <li>• Itching of the nose or throat</li> <li>• Itchy, watery eyes</li> </ul>	
<b>WARNINGS</b>	
Do not exceed recommended dosage. DO NOT USE IF PRINTED SAFETY SEAL IS MISSING OR BROKEN. Do not use this product.	
<ul style="list-style-type: none"> <li>• If you are now taking 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.</li> </ul>	
<ul style="list-style-type: none"> <li>• Ask a doctor before use if you have:               <ul style="list-style-type: none"> <li>• A cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema.</li> <li>• A cough that occurs with too much phlegm (mucus)</li> </ul> </li> <li>• Ask doctor or pharmacist before use if you are:               <ul style="list-style-type: none"> <li>• Taking sedatives or tranquilizers</li> <li>• If you have a breathing problem such as emphysema or chronic bronchitis</li> <li>• If you have glaucoma</li> <li>• If you have difficulty in urination due to enlargement of the prostate gland</li> </ul> </li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• Excitability may occur, especially in children.</li> <li>• Marked drowsiness may occur</li> <li>• Avoid alcoholic drinks</li> <li>• Alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>• Be careful when driving a motor vehicle or operating machinery</li> </ul>	

Drug Facts (continued)	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>• Nervousness, dizziness, or sleeplessness occurs</li> <li>• Symptoms do not improve within 7 days or are accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.</li> <li>• New symptoms occur</li> </ul>	
<b>If pregnant or breastfeeding</b>	
Ask a health professional before use.	
<b>Keep out of reach of children.</b>	
In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• Do not exceed recommended dosage.	
Adults and children 12 years of age and over:	2 teaspoonfuls (10mL) every 6 to 8 hours not to exceed 8 teaspoonfuls in 24hr
Children 6 to under 12 years of age:	1 teaspoonful (5mL) every 6 to 8 hours not to exceed 4 teaspoonfuls in 24hr
Children under 6 years of age:	Consult a doctor.
<b>Other Information</b>	
Store at 20° - 25°C (68° - 77°F); excursions permitted to 15°-30°C (59° - 86°F). [See USP Controlled Room Temperature.]	
<b>Inactive Ingredients</b>	
Citric Acid, Glycerin, Natural & Artificial Flavors, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sucralose.	
<b>Questions? Comments?</b>	
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23359-032-04

Ninjacof

Antitussive, Antihistamine

Each teaspoonful (5 mL) Contains:

Chlorpheniramine HCl.....12.5mg

Pyrilamine Maleate.....12.5mg

Alcohol Free Dye Free, Sugar Free

Cotton Candy Flavor

Centurion

16 fl oz (473 mL)

Manufactured for Centurion Labs, LLC Birmingham, AL 35243

Rev: 2/2015

EXP:

Lot:

## NINJACOF

chlorpheniramine hcl and pyrilamine maleate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:23359-032
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLOPHEDIANOL HYDROCHLORIDE</b> (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 5 mL
<b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	12.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COTTON CANDY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23359-032-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2014	
2	NDC:23359-032-10	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
3	NDC:23359-032-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/15/2014	

**Labeler** - Centurion Labs, LLC (016481957)