

NINJACOF- chlophedianol hcl and pyrillamine maleate solution
Centurion Labs, LLC

Ninjacof

OTC - ACTIVE INGREDIENT SECTION

Active ingredients (in each 5 ml) Purpose

Chlophedianol HCl 12.5 mg Antitussive
Pyrillamine 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.

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.

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[™]

Antitussive • Antihistamine

Each teaspoonful (5 mL) Contains:

Chlophedianol 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	
Active Ingredients (in each 5 mL (1 tsp))	Purpose
Chlophedianol HCl 12.5 mg.....	Antitussive
Pyrilamine Maleate 12.5 mg.....	Antihistamine
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	
• Runny Nose	
• Sneezing	
• Itching of the nose or throat	
• Itchy, watery eyes	
WARNINGS	
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	
When using this product	
• 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)	
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	
If pregnant or breastfeeding	
Ask a health professional before use	
Keep out of 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 (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
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 Ingredients	
Citric Acid, Glycerin, Natural & Artificial Flavors, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sucralose	
Questions? Comments?	
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:

Chlophedianol 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:

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:

23359-032-04

NinjacofTM

Antitussive • Antihistamine

Each teaspoonful (5 mL) Contains:

Chlophedianol 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

Active Ingredients (in each 5 mL (1 tsp))

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

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
- Runny Nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes

WARNINGS
 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'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, 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

When using this product

- 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)

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

If pregnant or breastfeeding
 Ask a health professional before use.

Keep out of 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 (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.

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

Questions? Comments?
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23359-032-04

Ninjacof

Antitussive, Antihistamine

Each teaspoonful (5 mL) Contains:

Chlophedianol 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

chlophedianol hcl and pyrilamine maleate solution

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

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)