# NINJACOF-A - ninjacof-a 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.

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Active Ingredients (in each 5 mL)	Purposes
Acetaminophen 160 mg	Pain Reliever
Chlophedianol HCl 12.5 mg	Antitussive
Pyrilamine Maleate 12.5mg	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
- calms the cough control center and relieves coughing
- itching of the nose or throat
- itchy, watery eyes
- minor aches and pains
- temporarily reduces fever
- runny nose
- sneezing
- headache

# **Warnings**

## Liver Warning; This product contains acetaminophen. Severe Liver damage may occur if:

- adult takes more than 6 teaspoonfuls in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product
- Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician
- May cause excitability especially in children

## Ask a doctor or pharmacist before you use

- if you are taking sedatives or tranquilizers
- if the user has liver disease
- if user is taking the blood thinning drug warfarin
- if cough persists for more than 1 week, tends to recur or is accompanied by fever, rash, or persistent headache.

# A persistent cough may be a sign of a serious condition

# When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks

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

# Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

# These could be signs of serious condition.

#### DO NOT USE

- with any other drug containing Acetaminophen (perscription or nonprescription).
- if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you do not know if your prescription contains an MAOI, ask a doctor or pharmacist before taking this product.
- unless directed by a doctor, if you have breathing problems such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to an enlargement of the prostate gland or for persistent or chronic cough such as occcurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)

If pregnant or breast-feeding, ask a health professional before use.

# Keep out of reach of children.

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

**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 (10mL) 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 (5mL) 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  $20^{\circ}$  -  $25^{\circ}$ C ( $68^{\circ}$ - $77^{\circ}$ F); excursions permitted to  $15^{\circ}$ -  $30^{\circ}$ C ( $59^{\circ}$ -  $86^{\circ}$ F). [See USP Controlled Room Temperature].

### **Inactive Ingredients**

Cotton Candy Flavor, Methylparaben, Polyethlyene Glycol 400, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, Sucralose

## **Questions? Comments?**

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

#### PRINCIPAL DISPLAY PANEL

23359-033-16

Ninja*cof<sup>TM</sup>-A* 

Pain Reliever • Fever Reducer • Antitussive • Anithistamine

Each teaspoonful (5mL) Contains:

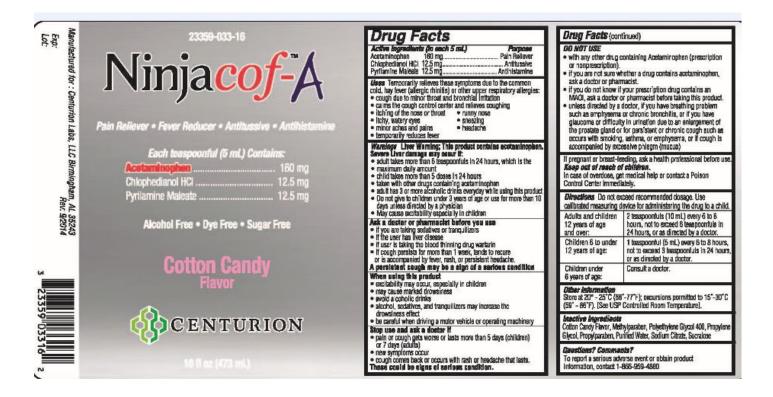
Acetaminophen.....160mg Chlophedianol HCI.....12.5mg Pyrilamine Maleate.....12.5mg

Alcohol Free • Dye Free • Sugar Free

**Cotton Candy** Flavor

**CENTURION** 

16 fl oz (473 mL)



# NINJACOF-A

ninjacof-a liquid					
<b>Product Information</b>					
Product Type	HUMAN OTC DRUG	Item Code (So	ource)	NDC:233	359-033
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Stre	ngth	Strength
					160 mg

Acetaminophen (UNII: 36209 ITL9D) (Acetaminophen - UNII: 36209 ITL9D)	Acetaminophen	in 5 mL
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		
Methylparaben (UNII: A2I8C7HI9T)			
Polyethylene Glycol 400 (UNII: B697894SGQ)			
Propylene Glycol (UNII: 6DC9Q167V3)			
Propylparaben (UNII: Z8IX2SC1OH)			
Water (UNII: 059QF0KO0R)			
Sodium Citrate (UNII: 1Q73Q2JULR)			
Sucralose (UNII: 96K6UQ3ZD4)			

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23359-033-16	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2014	

# Labeler - Centurion Labs, LLC (806756461)

# Registrant - Centurion Labs, LLC (806756461)

Revised: 11/2014 Centurion Labs, LLC