

NARAMIN - diphenhydramine hydrochloride solution
National Pharma Industries 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.

NARAMIN Antihistamine Oral Solution

NARAMIN Antihistamine Oral Solution

Active ingredient (per 5 ml = one pre-filled whistle)*

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

For the temporary relief of these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a sodium-restricted diet
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you

are taking sedatives or tranquilizers

When using this product

marked drowsiness may occur

avoid alcoholic beverages

alcohol, sedatives, and tranquilizers may increase the drowsiness effect

use caution when driving a motor vehicle or operating machinery

excitability may occur, especially in children

Choking Hazard: Small parts. Keep out of reach of children.

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 a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Adults and children 12 years of age and over	Take 2-4 pre-filled whistles every 4 to 6 hours, not to exceed 24 whistles in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age	Take 1-2 pre-filled whistles every 4 to 6 hours, not to exceed 12 whistles in 24 hours, or as directed by a doctor
Children under 6 years of age	Consult a doctor

Other information

- Each pre-fille whistle contains 14 mg of sodium
- Protect from light.
- SAFETY SEALED: This product is protected by a sealed pouch. Do not use if individual foil pouch is torn or damaged.
- Whistle is not child resistant. Do not remove whistle from child resistant foil pouch prior to use.
- Store between 68 degrees-77 degrees F (20 degrees - 25 degrees C)
- Store in outer carton until contents are used.

Inactive ingredients

anhydrous citric acid, DandC red no. 33, FDandC red no.40, flavor, glycerin, monoammonium glycyrrhizinate, poloxamer 407, sodium benzoate, sodium chloride, sodium citrate, sucrose, water

Questions or comments?

1-855-251-0106

NARAMIN Antihistamine Oral Solution 10-5ml whistles (58292-010-05)

Drug Facts

Active ingredient (per 5 ml = one pre-filled whistle)* Purpose
Diphenhydramine HCl 12.5 mg. Antihistamine

Uses
For the temporary relief of those symptoms due to hay fever or other upper respiratory allergies:
■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes

Warnings
Do not use
■ to relieve a cold/flu
■ with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ difficulty in urination due to enlargement of the prostate gland
■ a seizure-prone condition
Ask a doctor before use if you are taking medicine or tranquilizers
When using this product
■ motor vehicles may occur ■ avoid alcoholic beverages
■ alcohol, caffeine, and tranquilizers may increase the drowsiness effect
■ use caution when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children
Choking hazard: Small parts. Keep out of reach of small children.
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 a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Children 6 to under 12 years of age Take 1-2 pre-filled whistles every 4 to 6 hours, not to exceed 12 whistles in 24 hours, or as directed by a doctor
Children under 6 years of age Consult a doctor

Other information
■ Each pre-filled whistle contains 14 mg of sodium ■ Store between 60°-77° F (15°-25° C)
■ Protect from light ■ Store in each carton until contents are used
■ SAFETY SEALS: This product is protected by a sealed pouch. Do not use if individual foil pouch is torn or damaged.
■ Whistle is not child resistant. Do not remove whistle from child resistant foil pouch prior to use.

Inactive ingredients
polyethylene glycol, DSC-100, 30, DSC-100, No. 40, Benzoin glyceric, monomethylamine glycyrrhizinate, polyacrylate 417, sodium benzoate, sodium citrate, sodium chloride, sodium citrate, sucrose, water

Questions or comments? 1-855-251-0106

This product is not manufactured or distributed by McNeil
*Compare to Children's Benadryl Allergy Perfect Measure active ingredient



Antihistamine Oral Solution SINGLE-DOSE WHISTLES ALLERGY



1. Tear or Cut Foil to remove Naramin Single-Dose Allergy Medicated Whistle. Twist off cap.



2. Place Naramin Single-Dose Allergy Medicated Whistle into mouth and squeeze sides to dispense medication. Discard.

Manufactured for: National Pharma Industries
Address: 1155 Allogood Road, Suite-9,
Marietta, GA, 30062, USA



NDC 58292-010-05



Antihistamine Oral Solution SINGLE-DOSE WHISTLES ALLERGY

RELIEVES

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat

On The Go Allergy Relief
Perfect Dose



Cherry Flavor - Alcohol Free

10 Pre-Filled Single Dose Whistles**
0.17 fl oz (5 ml) EACH
Net 1.7 fl oz (50 ml)



**12.5 mg Diphenhydramine HCl each
*Compare to Children's Benadryl Allergy Perfect Measure active ingredient



Antihistamine Oral Solution SINGLE-DOSE WHISTLES ALLERGY

RELIEVES

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- itchy, watery eyes

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Do not use

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- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

- difficulty in urination due to enlargement of the prostate gland
- a sodium-restricted diet

Ask a doctor before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Choking Hazard: Small parts. Keep out of reach of small children.

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 a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Adults and children 12 years of age and over	Take 2 pre-filled whistles every 4 to 6 hours, not to exceed 24 whistles in 24 hours, or as directed by a doctor
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Other information

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- Whistle is not child resistant. Do not remove whistle from child resistant foil pouch prior to use.

Inactive ingredients

anhydrous citric acid, D&C red no. 33, FD&C red no. 40, flavor, glycerin, monoammonium glycyrrhizinate, poloxamer 407, sodium benzoate, sodium chloride, sodium citrate, sucrose, water

Questions or comments? 1-855-251-0108

Fold along dotted line, then tear at slit or use scissors

Whistle is not child resistant. Do not remove whistle from child resistant foil pouch prior to use.

NDC 58292-010-05



**Antihistamine
 Oral Solution**
SINGLE-DOSE WHISTLES
ALLERGY

RELIEVES On The Go Allergy Relief
 Perfect Dose

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat



Cherry Flavor - Alcohol Free

WARNING:
 CHOKING HAZARD - Small parts.
 Keep out of reach of small children.

**1 Pre-Filled Single
 Dose Whistle****

0.17 fl oz (5 ml)

**12.5 mg Diphenhydramine HCl each

Manufactured for: National Pharma Industries
 Address: 1155 Allgood Road, Suite-9,
 Marietta, GA, 30062, USA



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NARAMIN

diphenhydramine hydrochloride solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58292-010

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58292-010-05	10 in 1 PACKAGE		
1		5 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/28/2014	

Labeler - National Pharma Industries Inc (078725867)

Establishment

Name	Address	ID/FEI	Business Operations
Plastikon Healthcare, LLC		041717941	manufacture(58292-010)

