

ON THE GO-DOSE- diphenhydramine hydrochloride solution
Perfect Measure 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.

On The GO-Dose Diphenhydramine HCL Anti-Histamine Oral Solution

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

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 vial 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 vial 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 vial 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

On The GO-Dose Diphenhydramine HCL Anti-Histamine Oral Solution 12.5mg (58292-011-05)



SINGLE-DOSE VIALS
INDIVIDUALLY LABELED & PACKAGED

DIPHENHYDRAMINE HCL

**ANTIHISTAMINE
ORAL SOLUTION
ALLERGY**



1. Tear or cut child resistant safety foil pouch to remove GO-DOSE Diphenhydramine HCL single-dose vial. Twist off cap.



2. Place GO-DOSE Diphenhydramine HCL single-dose vial into mouth and squeeze sides to dispense medication. Discard after usage.

Manufactured for: Perfect Measure LLC
Marietta, GA 30062, USA



NDC 58292-011-05



SINGLE-DOSE VIALS
INDIVIDUALLY LABELED & PACKAGED

DIPHENHYDRAMINE HCL

**ANTIHISTAMINE
ORAL SOLUTION
ALLERGY**

On The Go
Allergy Relief

Compare to Children's
Benadryl® Allergy Perfect
Measure active ingredient.



Recommended by pediatricians

10 Pre-Filled Single-Dose vials
Individually labeled & packaged
0.17 fl oz (5ml) EACH
Net 1.7 fl oz (50ml)
12.5mg / 5ml



**ANTIHISTAMINE
ORAL SOLUTION
ALLERGY**

DIPHENHYDRAMINE HCL

RELIEVES

■ Sneezing ■ Runny nose ■ Itchy/watery eyes
■ Itchy throat or nose

On The Go
Allergy Relief



Recommended by pediatricians

**Compare to Children's Benadryl Allergy
Perfect Measure.**

10 Pre-Filled Single-Dose vials
Individually labeled & packaged

Drug Facts

Active ingredient (per 5 ml = one single-dose vial)* Purpose
Diphenhydramine HCl 12.5 mg. 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:
■ 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 medicine-restricted diet.

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

When using this product:

■ avoid alcoholic beverages ■ avoid alcoholic beverages
■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect
■ use caution when driving a motor vehicle or operating machinery
■ drowsiness 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 2-4 pre-filled vials every 4 to 6 hours, not to exceed 24 vials in 24 hours, or as directed by a doctor.

Children 6 to under 12 years of age:

Take 1-2 pre-filled vials every 4 to 6 hours, not to exceed 12 vials in 24 hours, or as directed by a doctor.

Children under 6 years of age:

Consult a doctor.

Other information

■ Each pre-filled vial contains 14 mg of sodium ■ Store between 68°-77° F (20°-25° C)
■ Protect from light. ■ Store in cooler container until contents are used
■ SAFETY: 256 ED. This product is packaged by a sealed pouch. Do not use if individual foil pouch is torn or damaged.
■ Vial is not child resistant. Do not remove vial from child resistant foil pouch prior to use.

Inactive ingredients

polyethylene glycol 400, SAC, red no. 33, FD&C red no. 40, flavor, glycerin, monosodiummonophosphate, poloxamer 407, sodium benzoate, sodium citrate, sodium chloride, 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.

Drug Facts

Active ingredient (per 5 ml = one single-dose vial)* **Purpose**
Diphenhydramine HCl 12.5 mg 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 ■ 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 2-4 pre-filled vials every 4 to 6 hours, not to exceed 24 vials in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age	Take 1-2 pre-filled vials every 4 to 6 hours, not to exceed 12 vials in 24 hours, or as directed by a doctor
Children under 6 years of age	Consult a doctor

Other information

- Each pre-filled vial contains 14 mg of sodium
- Store between 68°-77° F (20°-25° C)
- Protect from light. ■ Store in outer carton until contents are used.
- **SAFETY SEALED:** This product is protected by a sealed pouch. Do not use if individual foil pouch is torn or damaged.
- Vial 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? 1-855-251-0106

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

Vial is not child resistant. Do not remove vial from child resistant foil pouch prior to use.

NDC 58292-011-05

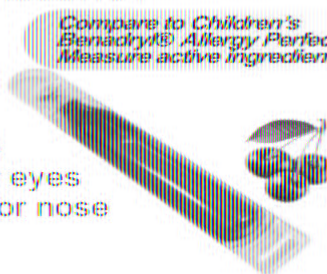


SINGLE-DOSE VIALS
INDIVIDUALLY LABELED & PACKAGED
DIPHENHYDRAMINE HCL
ANTIHISTAMINE
ORAL SOLUTION
ALLERGY

Compare to Children's Benadryl® Allergy Perfect Measure active ingredient

RELIEVES

- Sneezing
- Runny nose
- Itchy/watery eyes
- Itchy throat or nose



Cherry Flavor - Alcohol Free

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

1 Pre-Filled Single Dose Vial*

0.17 fl oz (5 ml)

*12.5 mg Diphenhydramine HCl each

Manufactured for: Perfect Measure LLC
Marietta, GA, 30062, USA

ON THE GO-DOSE

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58292-011
Route of Administration	ORAL		

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:58292-011-05	10 in 1 PACKAGE	01/31/2017	
1		5 mL in 1 VIAL; Type 0: Not a Combination Product		

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

Labeler - Perfect Measure LLC (080502613)

Registrant - Perfect Measure LLC (080502613)

Establishment			
Name	Address	ID/FEI	Business Operations
Horizon Pharmaceuticals, Inc.		960418825	manufacture(58292-011)

