

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride solution
Oncor Pharmaceuticals

Diphenhydramine Hydrochloride Solution

Active ingredients (in each 5 mL teaspoonful)	Purpose
Diphenhydramine Hydrochloride 12.5mg	Antihistamine

Uses

- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

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
- trouble urinating due to an enlarged prostate gland
- 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 drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Directions

- take every 4 to 6 hours or as directed by a doctor
- do not take more than directed
- mL=milliliter
- find right dose on chart below

Children under 2 years	Do not use
Children 2 to 5 years	Ask a doctor
Children 6 to 11 years	1-2 teaspoonful
Adults and children 12 years and over	2-4 teaspoonful

Inactive ingredients

citric acid, flavor, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose.

Other information

- each 1 tsp (5mL) contains: sodium 4 mg
- store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature]. Protect from freezing.
- tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Keep out of reach of children.

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Questions?

You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.

Principal Display Panel

Oncor Pharmaceuticals

NDC 83720-502-16

Diphenhydramine Hydrochloride
Oral Solution

12.5 mg/5 ml

Antihistamine

Cherry Flavor

RELIEVES

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat due to Allergies

DO NOT USE IF TAMPER EVIDENT SEAL
UNDER CAP IS BROKEN OR MISSING

Alcohol Free

NET WT. 16 OZ. (473 ml)

NDC 83720-502-04

Diphenhydramine Hydrochloride
Oral Solution

12.5 mg/5 ml

Antihistamine

Cherry Flavor

RELIEVES

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat due to Allergies

DO NOT USE IF TAMPER EVIDENT SEAL
UNDER CAP IS BROKEN OR MISSING

Alcohol Free

NET WT. 4 OZ. (118 ml)

Manufactured In USA For :

Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.

Rev. 03/25

NCOR
PHARMACEUTICALS
NDC 83720-502-16

Diphenhydramine Hydrochloride Oral Solution
12.5 mg/5 ml
Antihistamine
Cherry Flavor

RELIEVES

- Sneezing
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- Itchy Throat due to Allergies

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DRUG FACTS

Active ingredients
(in each 5 mL teaspoonful)

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DRUG FACTS (continued)

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Manufactured in USA For :
Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 03/25

Lot:
Exp:

NCOR
PHARMACEUTICALS
NDC 83720-502-04

Diphenhydramine Hydrochloride Oral Solution
12.5 mg/5 ml
Antihistamine
Cherry Flavor

RELIEVES

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat due to Allergies

DO NOT USE IF TAMPER EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING

Alcohol Free

NET WT. 4 OZ. (118 ml)

Drug Facts

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(in each 5 mL teaspoonful)

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Manufactured In USA For :
Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 03/25



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DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83720-502
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
CITRIC ACID (UNII: 2968PHW8QP)	
CHERRY (UNII: BUC5I9595W)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-502-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2025	
2	NDC:83720-502-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/27/2025	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)