

**DIPHENHYDRAMINE HCL ORAL SOLUTION- diphenhydramine hydrochloride solution**  
**Natco Pharma USA LLC**

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**Diphenhydramine HCl Oral Solution, USP**

***Drug Facts***

**Active ingredient (in each 5 mL)**

Diphenhydramine HCl USP 12.5 mg

**Active ingredient (in each 10 mL)**

Diphenhydramine HCl USP 25 mg

**Purpose**

Antihistamine

**Uses**

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

**Warnings**

**Do not use**

• in neonates or premature infants • if pregnant or breast-feeding • if hypersensitive to diphenhydramine HCl and other similar antihistamine • with any other product containing diphenhydramine, even one used on skin • to make a child sleepy

**Ask a doctor before use if you have**

• glaucoma • a breathing problem such as emphysema or chronic bronchitis  
• a sodium restricted diet • trouble urinating due to enlarged prostate gland

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

**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

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

## Directions

- Use the following dosage guidelines when using this product

Age (yr)	Dose (mL)
Adults and children 12 years and older	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours.
Children 6 years to under 12 years	take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours
Children under 6 years	ask a doctor

## Other information

- each 5mL contains sodium 10mg
- each 10mL contains sodium 20mg
- alcohol free, cherry flavor
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- see top of cup for lot number and expiration date

## Inactive ingredients

Citric acid, D&C Red No. 33, FD&C Red No. 40, flavor, glycerin, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, and sucrose.

## How Supplied

**Each 5 mL** of Diphenhydramine Hydrochloride Oral Solution, USP contains 12.5mg diphenhydramine hydrochloride and is supplied in the following oral dosage forms:

<b>NDC 69339-151-05</b>	<b>(1) unit dose cup</b>	<b>5mL</b>
<b>NDC 69339-151-17</b>	<b>40 (4x10) unit dose cups</b>	<b>5mL</b>
<b>NDC 69339-151-19</b>	<b>100 (10x10) unit dose cups</b>	<b>5mL</b>

**Each 10 mL** of Diphenhydramine Hydrochloride Oral Solution, USP contains 25mg diphenhydramine hydrochloride and is supplied in the following oral dosage forms:

<b>NDC 69339-152-01</b>	<b>(1) unit dose cup</b>	<b>10mL</b>
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**NDC 69339-152-17**  
**NDC 69339-152-19**

**40 (4x10) unit dose cups**  
**100 (10x10) unit dose cups**

**10mL**  
**10mL**

**Questions or comments?**

Call 201-786-6500

Dash Pharmaceuticals LLC  
Upper Saddle River, NJ 07458

DP-UD-PI-AT-[117894] Rev 08/20

**PRINCIPAL DISPLAY PANEL**

Delivers 5 mL

NDC 69339-151-05

**Diphenhydramine HCl Oral Solution, USP**

**12.5 mg/5 mL**

For Institutional Use Only

3 69339 15105 1

Lot # 000000

Exp: MM/YYYY

See Insert

DASH Pharmaceuticals LLC

Upper Saddle River, NJ 07458

DASH-

DOSE

Delivers **5 mL**

NDC 69339-151-05

**Diphenhydramine HCL  
Oral Solution, USP**

**12.5mg/5mL**

**For Institutional Use Only**



Lot# 000000

Exp: MM/YYYY

**See Insert**

DASH Pharmaceuticals LLC

Upper Saddle River, NJ 07458

**DASH-  
DOSE**

**PRINCIPAL DISPLAY PANEL**

Delivers 10 mL

NDC 69339-152-01

Diphenhydramine HCl Oral Solution, USP

25 mg/10 mL

For Institutional Use Only

3 69339 15201 0

Lot # 000000

Exp: MM/YYY

See Insert

DASH Pharmaceuticals LLC

Upper Saddle River, NJ 07458

DASH-

DOSE

Delivers **10 mL**

NDC 69339-152-01

**Diphenhydramine HCL  
Oral Solution, USP**

**25mg/10mL**

**For Institutional Use Only**



Lot# 000000

Exp: MM/YYYY

**See Insert**

DASH Pharmaceuticals LLC  
Upper Saddle River, NJ 07458

***DASH-  
DOSE***<sup>™</sup>

## DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69339-151
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KOOR)	

<b>SUCROSE</b> (UNII: C151H8M554)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69339-151-17	4 in 1 CASE	12/14/2020	
1		10 in 1 TRAY		
1	NDC:69339-151-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:69339-151-19	10 in 1 CASE	12/14/2020	
2		10 in 1 TRAY		
2	NDC:69339-151-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/14/2020	

## DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69339-152
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	25 mg

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

HYDROCHLORIDE

in 10 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69339-152-17	4 in 1 CASE	12/14/2020	
1		10 in 1 TRAY		
1	NDC:69339-152-01	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:69339-152-19	10 in 1 CASE	12/14/2020	
2		10 in 1 TRAY		
2	NDC:69339-152-01	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/14/2020	

**Labeler** - Natco Pharma USA LLC (079590418)