

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule  
Lake Erie Medical DBA Quality Care Products LLC**

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**Active Ingredient (in each banded capsule)**

Diphenhydramine HCl... 25 mg

Diphenhydramine HCl... 50 mg

**Purpose**

Antihistamine

**Use**

25 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itchy throat and nose
- Temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

50 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold
  - sneezing
  - runny nose
  - itchy, watery eyes
  - itchy throat and nose

**WARNINGS**

**Do not use**

25 MG

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

50 MG

- to make a child sleepy
- with any other product containing diphenhydramine, including one applied topically

## Ask a doctor before use if you have

### 25 MG

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

### 50 MG

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

## 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.

## KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

## 25 MG

adults and children 12 years of age and over	1 to 2 capsules
children 6 years to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age

## 50 MG

adults and children 12 years of age and over	1 capsule
children 6 years to under 12 years of age	Ask a doctor, the proper dosage strength is not available in this package**

\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

### Other Information

- Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]
- Protect from moisture
- Contains lactose

### Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

### Questions?

Questions or comments? (800) 616-2471

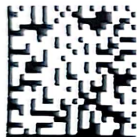
### Distributed by

MAJOR® PHARMACEUTICALS  
17177 N Laurel Park Drive, Suite 233,  
Livonia, MI 48152

Packaged and Distributed by *Quality Care Products, LLC* 1-800-337-8603

Store at room temperature, USP

Holland, OH 43528



GTIN: 00355700580308  
NDC: 55700-580-30  
Serial:  
Lot:  
EXP: //

**BANOPHEN 25 mg**  
**Diphenhydramine HCl**

**#30 Capsules**  
**ANTIHISTAMINE**

Active ingredient (in each banded capsule) Diphenhydramine HCl 25 mg.

Keep all medication out of reach of children



Distributed by: MAJOR PHARMACEUTICALS  
17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55700-580(NDC:0904-5306)
<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	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	PINK (half pink and half clear with white powder inside)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;835
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55700-580-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2018	10/11/2019
2	NDC:55700-580-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2018	04/30/2025

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	01/12/2018	04/30/2025

**Labeler** - Lake Erie Medical DBA Quality Care Products LLC (831276758)

## Establishment

Name	Address	ID/FEI	Business Operations
Lake Erie Medical DBA Quality Care Products LLC		831276758	repack(55700-580)

Revised: 12/2023

Lake Erie Medical DBA Quality Care Products LLC