

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule  
St. Mary's Medical Park Pharmacy**

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**0835&0836(box unit)-Major**

**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

NDC 60760-332-30

**Diphenhydramine  
HCl (BANOPHEN)  
CAPSULES  
25 mg**

QTY: 30  
LOT# XXXXXXXX  
EXP XX-XX  
RX# ????????

MANUFACTURED BY:  
MAJOR PHARMACEUTICALS  
Livonia, MI 48152

60760-332-30



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HCl (BANOPHEN)  
CAPSULES**

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NDC 60760-332-30  
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HCl (BANOPHEN)  
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**25 mg**  
QTY: 30  
RX# ????????  
NDC 60760-332-30  
LOT# XXXXXXXX  
EXP XX-XX

**TAKE AS DIRECTED  
MAY CAUSE DROWSINESS**



**PACKAGED BY:**  
**St. Mary's**  
10660 MAVINEE DR.  
ORO VALLEY, AZ 85737  
MANAGED PHARMACY PROGRAMS

**Rx only** STORE AT CONTROLLED ROOM TEMPERATURE 15°- 30° C (59°-86°F)

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60760-332(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 MONOHYDRATE</b> (UNII: EWQ57Q815X)	
<b>STARCH, CORN</b> (UNII: O8232NY35J)	

### 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:60760-332-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/11/2020	

**Labeler** - St. Mary's Medical Park Pharmacy (063050751)

## Establishment

Name	Address	ID/FEI	Business Operations
St. Mary's Medical Park Pharmacy		063050751	relabel(60760-332) , repack(60760-332)

Revised: 12/2023

St. Mary's Medical Park Pharmacy