DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule Preferred Pharmaceuticals Inc.
0835K- Major
Drug Facts
Active ingredient (in each capsule) Diphenhydramine HCl 25 mg
<b>Purpose</b> Antihistamine
Uses
$\  \  \  \  \  \  \  \  \  \  \  \  \  $
☐ to make a child sleepy
$\hfill \square$ with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have  ☐ a breathing problem such as emphysema or chronic bronchitis
☐ glaucoma ☐ trouble urinating due to an enlarged prostate gland
Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
When using this product
☐ marked drowsiness may occur
<ul><li>□ avoid alcoholic drinks</li><li>□ alcohol, sedatives and tranquilizers may increase drowsiness</li></ul>
☐ 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 (1-800-222-1222).
Directions
☐ take every 4 to 6 hours, or as directed by a doctor
☐ do not take more than 6 doses in 24 hours

adults and children	1 to 2 capsules
12 years of age and over	
children 6 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

#### Other information

 $\square$  store in a dry place at 15° – 30°C (59° – 86°F)

corn starch, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate

#### **Ouestions or comments?**

1-800-616-2471

Distributed by: MAJOR® PHARMACEUTICALS, Indianapolis, IN 46268

Product of China. Manufactured and packaged in the USA using domestic and imported ingredients.

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl®.

To preserve quality and freshness, keep bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF PRODUCT APPEARS TO BE TAMPERED WITH OR IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING. DO NOT USE IF RED CAPSULE BAND IS BROKEN OR MISSING.

Major

**BENOPHEN** 

NDC 0904-7237-80

Complete Allergy Medication

Diphenhydramin HCl 25 mg

**Antihistamine** 

For the temporary relief of the symptoms of:

- Upper Respiratory Allergies
- Hay Fever

Compare to the active ingredient in BENADRYL®\*

EACH CAPSULE INDIVIDUALLY BANDED FOR YOUR PROTECTION

Repackaged By: Preferred Pharmaceuticals Inc.

### Diphenhydramine HCL Capsules, USP 25mg

USP 25mg Generic for Benadryl

Active ingredient(in each capsule): Diphenhydramine HCL 25mg...Antihistamine

Pkg Size: Exp Date: ##/#####

Lot#: Batch#:

Ins:

Mfg: Major Pharmaceuticals Prod#:

Warning
Store in a dry place at 15°- 30°C (55°- 36°F). Do not use
to make a child sleepy, with up, other product containing
Diphen hydramine HCI, including one applied topically.
Ask a doctor before use if you have gladeoma, frouble
urnating due to an enlarged prostate gland, a breathing
problem such as emphysema or chronic bronchist, or fil
you are laking sedatives or tranquilizers. Keep this and all
problem such as emphysema or floronic bronchist, or fil
you are laking sedatives or tranquilizers. Keep this such
problem such as emphysema or floronic bronchist, or fil
you are laking sedatives or tranquilizers. Keep this such
gas, as a such in professional before use.
Capsule is pinkand clear, and imprinted with CPC 835.





CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.



GTIN ########## SN ###### EXP ##/#####EXP Instrucciones Espanol:

Toma\_\_\_\_\_ capsula(s)

cada\_\_\_\_ horas.

Puede causar
somnolencia.

No tome bebidas
alcoholicas mientras
toma esta medicina.

Diphenhydramine HCL Capsules, USP 25mg Qty: Ins: Lot: Bat:

Prod# (NDC):

Log

Diphenhydramine HCL Capsules, USP 25mg Qty: Ins: Lot: Bat: Prod# (NDC):

Diphenhydramine HCL Capsules,
USP 25mg
Qty:
Insurance NDC:
Lot: Bat:

Diphenhydramine HCL Capsules, USP 25mg Qty: Ins: Lot: Bat: Prod# (NDC):

#### DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68788-8855(NDC:0904-7237)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)
(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

25 mg

Inactive Ingredients			
Ingredient Name	Strength		
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
STARCH, CORN (UNII: 08232NY3SJ)			

Product Characteristics			
Color	pink (Half pink and half clear with white powder inside and sealed with red band)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;835
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788- 8855-0	10 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2025	
2	NDC:68788- 8855-1	15 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2025	
3	NDC:68788- 8855-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/11/2025	

# **Labeler -** Preferred Pharmaceuticals Inc. (791119022)

## Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8855)	

Revised: 4/2025 Preferred Pharmaceuticals Inc.