

BANOPHEN- diphenhydramine hcl capsule
Preferred Pharmaceuticals Inc.

0836-Major(100C/1000C)

Active Ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Use

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
 - o runny nose
 - o sneezing

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
- a breathing problem such as emphysema or chronic bronchitis
- 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
- 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

adults and children 12 years of age and over	Take 1 capsule (50 mg)
children 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 room temperature, USP.
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- 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

Repackaged By: Preferred Pharmaceuticals Inc.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p style="background-color: yellow; padding: 5px;">Diphenhydramine HCL Capsules, USP 50mg</p> <p>Generic for: Benadryl</p> <p>Each capsule contains: Diphenhydramine HCL 50mg</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Major Pharm.; Livonia, MI Prod#:</p> <p>Warning <small>Store at room temperature 0° to 25°C (68° to 77°F). Protect from moisture. Do not use with any other product containing Diphenhydramine HCL, including uses applied topically. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Ask a doctor or pharmacist before use if you have trouble urinating, due to enlarged prostate gland, a breathing problem such as emphysema or chronic bronchitis, glaucoma, or if you are taking sedatives or tranquilizers. Capsule is pink and imprinted with CPC 836.</small></p>	 <p style="font-size: 8px;">Approved by FDA</p>	<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Diphenhydramine HCL Capsules, USP 50mg Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC):</p> <p>Diphenhydramine HCL Capsules, USP 50mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Diphenhydramine HCL Capsules, USP 50mg Qty: Insurance NDC: Lot#: Bat#:</p> <p>Diphenhydramine HCL Capsules, USP 50mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p style="text-align: right;">Log</p> <p style="text-align: right;">Chart</p> <p style="text-align: right;">Billing</p> <p style="text-align: right;">Patient</p>
 <p style="font-size: 8px;">Directions English</p> <p>May cause drowsiness. Do not drink alcohol taking this medicine. Take _____capsule(s) every _____hours.</p>		<p style="font-size: 8px;">Instrucciones Español:</p> <p>Puede causar somnolencia. No tome bebidas alcoholicas mientras toma esta medicina. Toma _____capsula(s) cada _____horas.</p>		

BANOPHEN			
diphenhydramine hcl capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7830(NDC:0904-5307)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 28 (UNII: 767IP0Y5NH)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	pink	Score	no score

Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;836
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7830-1	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2021	
2	NDC:68788-7830-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	341	01/08/2021	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-7830)

Revised: 1/2024

Preferred Pharmaceuticals Inc.