DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule Preferred Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25mg and 50mg

Drug Facts

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Active Ingredient

(in each capsule)

Diphenhydramine HCl 25 mg

Diphenhydramine HCl 50 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- itchy nose or throat
- sneezing
- itchy, watery eyes

WARNINGS

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers **When using this product**

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives & 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

- **adults and children 12 years and over:** take 1 to 2 capsules every 4-6 hours; not more than 6 doses in 24 hours
- children under 12 years: ask a doctor

Other Information

Diphenhydramine 25mg

Bottle of 30 - 68788-9697-3

Diphenhydramine 50mg

Bottle of 30 - 68788-9698-3

- store at 15-30 °C (59-86 °F)
- protect from moisture
- Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP

Inactive Ingredients

benzyl alcohol, butylparaben, D&C red# 28, edible black ink, FD&C blue #1, FD&C red# 40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium laurel sulfate

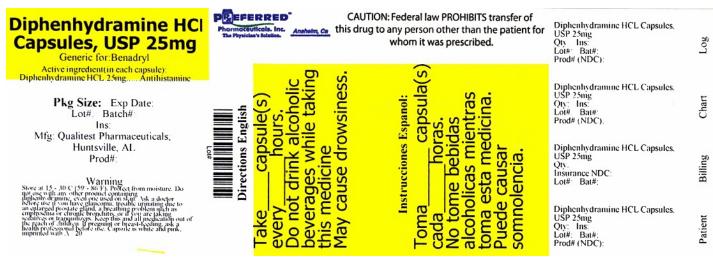
Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED

Distributed by: Qualitest Pharmaceuticals, Inc.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 25 MG

ANTIHISTAMINE



DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 50 MG ANTIHISTAMINE

Diphenhydramine HCI

Capsules, USP 50mg
Generic for: Benadryl
Each capsule contains: Diphenhydramine HCL
50mg

Pkg Size: Exp Date: Lot#: Batch#; Ins: Mfg: Qualitest Pharmaceuticals; Huntsville, AL Prod#:

Warning and a doctor before use if you have glateoma trouble turngting due to an enlarged prostate dand, a preathing problem such as emphysein or closic bronchine, or other problem, and the problem of the problem of



capsule(s) Directions English

every

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

> capsula(s) alcoholicas mientras Instrucciones Espanol: toma esta medicina cada horas. No tome bebidas Puede causar somnolencia. Toma

Diphenhydramine HCL Capsules. USP 50mg Qty: Ins: Loi#: Bat#: Prod# (NDC):

Log

Chart

Patient

Diphenhydramine HCL Capsules, USP 50mg Qty. Ins: Lot#: Bat#: Prod# (NDC):

Diphenhydramine HCL Capsules, USP 50mg Qty Insurance NDC: Lot#: Bat#:

Diphenhydramine HCL Capsules. USP 50mg Qty: Ins: Loi# Bat#: Prod# (NDC):

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68788- 9697(NDC:0603-3339)
Route of Administration	ORAL	DEA Schedule	

beverages while taking this medicine May cause drowsiness.

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL		
BUTYLPARABEN		
D&C RED NO. 28		
FD&C BLUE NO. 1		
FD&C RED NO. 40		
GELATIN		
LACTOSE		
MAGNESIUM STEARATE		
METHYLPARABEN		
POLYSORBATE 80		
PROPYLPARABEN		
SO DIUM LAURYL SULFATE		

Product Characteristics			
Color	PINK	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;020

Contains

P	acl	kag	ing

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:68788-9697-3	30 in 1 BOTTLE		

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final part341 03/19/2013

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68788- 9698(NDC:0603-3340)

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

inderve ingredients	
Ingredient Name	Strength
BENZYL ALCOHOL	
BUTYLPARABEN	
D&C RED NO. 28	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GELATIN	
LACTOSE	
MAGNESIUM STEARATE	
METHYLPARABEN	
POLYSORBATE 80	
PROPYLPARABEN	
SODIUM LAURYL SULFATE	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;021

Contains Packaging Item Code Package Description **Marketing Start Date Marketing End Date** 1 NDC:68788-9698-3 30 in 1 BOTTLE **Marketing Information Marketing Category** Application Number or Monograph Citation Marketing Start Date Marketing End Date part341 OTC monograph final 03/19/2013

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	REPACK(68788-9697, 68788-9698)

Revised: 11/2013 Preferred Pharmaceuticals, Inc.