#### DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule Epic Pharma, LLC

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.

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## DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25 mg

## **ACTIVE INGREDIENT (IN EACH CAPSULE)**

Diphenhydramine HCl 25 mg

#### PURPOSE

Antihistamine

#### USES

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

- runny nose
- sneezing
- itchy nose or throat
- 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**

- Iglaucoma
- 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 tranquizers

#### **When using this product**

- Iyou may get very drowsy
- 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-feedingI**, ask a health professional before use.

## KEEP OUT OF THE REACH OF CHILDREN.

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

#### DIRECTIONS

• adults & children 12 years and over: take 1-2 capsules every 4-6 hours; not more than 6 does in 24 hours

• Ichildren under 12 years: ask a doctor

#### **OTHER INFORMATION**

- store at 15°-30°C (59°-86°F)
- protect from moisture
- This is a bulk package. 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 lauryl sulfate

#### **QUESTIONS OR COMMENTS?**

call **888-374-279 1**, 8:30 am - 4:30 pm ET, Monday - Friday

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

Distributed by:

Epic Pharma, LLC

Laurelton, NY

11413

#### PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 25 MG

#### Diphenhydramine HCl Capsules, USP 025 mg

#### **ANTIHISTAMINE**

**1000** Capsules

#### **THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

NDC 42806-648-10 *Compare to active ingredient in BENADRYL® Allergy THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN	Purpose         Fever or other upper         hy, watery eyes         for prostate gland         nic bronchtits         g sedatives or tranquilizers         nic bronchtits         of machinery         onal before use.         get medical help or         get medical help or         ask a doctor         ask a doctor         oisture         in the USP         on Lachmerstant         in the USP         of MAMAGE         of MAMAGE         mark BERMORNU® Allergy.         mark BERMORNU® Allergy.	
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Capsules, USP	Anti f hay fever or other L eitchy, watery eyes ydramine, even one us ydramine, even one us itchy, watery eyes drinks arged prostate glann chronic bronchtils laking sedatives or tr drinks asse drowsiness erating machinery fessional before use. I -2 capsules ask a doctor m moisture a tight, light-resistar fined in the USP paraben, D&C red #2 baraben, D&C red #2 lactuse, ringmesium softium lauryl suffate 0 am - 4:30 pm ET, Mon	
25 mg Antihistamine	ch capsule) ch capsule) se symptoms of unny nose neozining diphent have ng due to an en thave ng due to an en thave ng due to an en thave is emphysema or thave is emphysema or thave are of allo that avoid alcoholic to the are to the are allo to the are allo to the are are of over to that avoid allo to the are allo to the a	No Varnish
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Distributed by: Epic Pharma, LLC Laurelton, NY 11413	Drug Facts Active ingredient (in ea Diphenhydramine HCI 25 mg. Uses temporarily relieves the respiratory allergies: Uses temporarily relieves the respiratory allergies: s Warnings Warnings Warnings a breathing problem such as glauconca before use if you a breathing problem such as take a doctor or pharmacist befo When using this product a breathing may devery drowsy action is set way drowsy action is each of children. Excitability may occur, espec th pregnant or breast-leeting, when using this product be careful when driving a mo excitability may occur, espec excitability may occur, espec th pregnant or breast-leeting, the pregnant or breast-leeting, the pregnant or breast-leeting, the pregnant or breast-leeting, adults & children. Container with a child-resista functive ingredients ben black ink, FD&C blue #1, FD&C methybaraben, polysorbate 80. Ouestions or comments? call rametrive ingredients ben black ink, FD&C blue #1, FD&C methybaraben, polysorbate 80. Ouestions or comments? call rametrive intervent. E0 is extined to the forma, LLC is not affiliated *Epic Pharma, LLC is not affiliated *Cented at 15 * 20°C (59 * 80 * 7	Lot No.: Exp. Date:

# DIPHENHYDRAMINE HYDROCHLORIDE

Product Informat	tion							
Product Type		HUMAN OTC DRUG Item Code (So			ource)	ce) NDC:42806-648		
Route of Administra	tion	ORAL						
Active Ingredient	t/Active M	oie ty						
Ingredient Name					Basis of Strength Stre		Strengt	
<b>DIPHENHYDRAMINE HYDRO CHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRA UNII:8GTS82S83M)					DIPHENHYDRAMINE HYDROCHLORIDE 25 mg		25 mg	
Inactive Ingredie	nts							
		Ingredient	Name			Str	Strength	
BENZYL ALCOHOL (	UNII: LKG849	4WBH)						
BUTYLPARABEN (UN								
D&C RED NO. 28 (UN								
FD&C BLUE NO. 1 (U)								
FD&C RED NO. 40 (U)		KUA)						
GELATIN (UNII: 2G86) LACTOSE (UNII: J2B2								
MAGNESIUM STEARA	· · ·	97M6I30)						
METHYLPARABEN (U								
POLYSORBATE 80 (U								
PROPYLPARABEN (U	NII: Z8IX2SC1	ОЮ						
		011)						
SODIUM LAURYL SU								
	LFATE (UNII:							
	LFATE (UNII:							
Product Characte Color	LFATE (UNII: eristics pink	368GB5141J)	Score			no score		
<b>Product Characte</b> Color Shape	LFATE (UNII: eristics	368GB5141J)	Size			14mm		
<b>Product Characte</b> Color Shape Flavor	LFATE (UNII: eristics pink	368GB5141J)		le				
<b>Product Characte</b> Color Shape Flavor	LFATE (UNII: eristics pink	368GB5141J)	Size	le		14mm		
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Product Characte Color Shape Flavor Contains Packaging	LFATE (UNII: eristics pink	368GB5141J)	Size Imprint Cod			14mm AP;020	ng End Date	
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Revised: 11/2016

Epic Pharma, LLC