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.

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 50 mg

ACTIVE INGREDIENT (IN EACH CAPSULE)

Diphenhydramine HCl 50 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 capsule 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 - 50 MG

Diphenhydramine HCl Capsules, USP 050 mg

ANTIHISTAMINE

1000 Capsules

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

NDC 42806-649-10 "Compare to active ingredient in BENADRYL® Allergy "Compare to active ingredient in BENADRYL® Allergy "Compare to active ingredient	Purpose fever or other upper hy, watery eves hy, watery eves hy, watery eves hy, watery eves d prostate gland inic bronchitis g sedatives or tranquilizers vs drowsiness inic bronchitis onal hefore use. get medical help or get medical help or ask a doctor ask a doctor oisture ht, light-resistant in the USP ben. D&C red #28, edible wm Buwlinkto Aubergy. mark BERWORVLE Aubergy. mark BERWORVLE Aubergy.
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Capsules, USP	ay fever or tictry nose tictry, wate itchy, wate ironic bron innks sed prostal innks sed prostal and mach at nonic bron and mach innks e drowsine as a do more than 6 more than 7 more tha
50 mg	s of h s of h
ANTIHISTAMINE	Active ingredient (in each capsule Diphenhydramine HCI 50 mg
1000 Capsules	ingredient (in the HCI 50 temporarily relieve to yudramine HCI 50 temporarily relieve to yudramine HCI 50 temporarily relieve to yudramine HCI 50 temporarily relieve to the service and the service trouble us to the service to the
Distributed by: Epic Pharma, LLC Laurelton, NY 11413	Diphenhydramine HCI 50 m Diphenhydramine HCI 50 m Diphenhydramine HCI 50 m Uses temporarity relieves respiratory allergiles: Uwarnings Warnings Do not use with any other prodo ask a doctor before use if y dy when using this product ask a doctor or pharmacist b When using this product as a breathing problem such according this product contact a Poison Control Ce Directions a bulk package Di container with a childrens the store at 15°-30°C (59°-86 methylparaben, polysorbate Discrive ingredients t black ink, FD&C blue #1, FD methylparaben, polysorbate Discrive ingredients t Duestions or comments??

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule									
Product Information									
	L								
Product Type		HUMAN OTC DR	UG	Item Code (S	ource)	NDC:42806-649			
Route of Administration	I	ORAL							
Active Ingredient/Active Moiety									
Ingredient Name Basis of St						trength	Strength		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMI UNII:8GTS82S83M) DIPHENHYDRAMINE - HYDROCHLORIDI							50 mg		
Inactive Ingredients									
Ingredient Name							Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)									
BUTYLPARABEN (UNII: 3QPI1U3FV8)									
D&C RED NO. 28 (UNII: 767IP0 Y5NH)									
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)									
FD&C RED NO. 40 (UNII: V									
GELATIN (UNII: 2G86QN327L) LACTOSE (UNII: J2B2A4N98G)									
MAGNESIUM STEARATE (UNII: 70097M6I30)									
METHYLPARABEN (UNII: A2I8C7HI9T)									
POLYSORBATE 80 (UNII: 60ZP39ZG8H)									
PROPYLPARABEN (UNII: Z8IX2SC10H)									
SODIUM LAURYL SULFATE (UNII: 368GB5141J)									
Product Characteris	tics								
Color	pink		Score			no score			
Shape	capsul	e	Size		14mm				
Flavor			Imprint Cod	le		AP;021			
Contains									
Packaging									
# Item Code		Package Description		Mar	keting Start Dat	Marketing End Date			
1 NDC:42806-649-10 100	0 in 1 BOTT	OTTLE; Type 0: Not a Combination Product		Product 11/22/	11/22/2016				
Marketing Information									
Marketing Category	rketing Category Application Number or Monograph Citation Marke				keting Start Date	Marketing	End Date		
OTC monograph final p	art341			11/22/2	2016				

Revised: 11/2016

Epic Pharma, LLC