

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**

- ☐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 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 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

- Children 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 1-888-374-2791, 8:30 am - 4:30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY 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 50 mg

ANTI-HISTAMINE

1000 Capsules

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

NDC 42806-649-10		THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN	
*Compare to active ingredient in BENADRYL® Allergy			
Diphenhydramine HCl Capsules, USP			
50 mg			
ANTI-HISTAMINE			
1000 Capsules			
Distributed by: Epic Pharma, LLC Laurelton, NY 11413			
Drug Facts			
Active ingredient (in each capsule) Diphenhydramine HCl 50 mg		Purpose Antihistamine	
Uses temporarily relieves these symptoms of hay fever or other upper respiratory allergies:		<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> you 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-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		<ul style="list-style-type: none"> take every 4-6 hours do not take more than 6 doses in 24 hours adults & children 12 years and over 1 capsule children under 12 years ask a doctor 	
Other information		<ul style="list-style-type: none"> 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	
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*Epic Pharma, LLC is not affiliated with the owner of the trademark BENADRYL® Allergy.			
LEP 1016			
Lot No.:		4 2 8 0 6 - 6 4 9 - 1 0 1 7	
Exp. Date:		LE3492	
		No Varnish	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42806-649
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

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:42806-649-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/22/2016	

Labeler - Epic Pharma, LLC (827915443)

