

DIPHENHYDRAMINE - diphenhydramine hydrochloride capsule
H.J. Harkins Company, 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

Active ingredient

Diphenhydramine Hydrochloride 50mg

Purpose

Antihistamine

Use

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold, sneezing, runny nose, itchy, watery eyes, itchy throat and nose.

Warning

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 tranquilizers or sedatives.

When using this product

you may get 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. Do not use any other products containing diphenhydramine.

Pregnancy/breast-feeding warning

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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 25 to 50 mg (1 to 2 capsule) every 4 to 6 hours; not more than 12 capsules in 24 hours.

Children 6 years to 12 years of age: take 25 mg (1 capsule) every 4 to 6 hours; not more than 6 capsules in 24 hours.

Children under 6 years of age: ask a doctor.

Other information

Store at controlled room temperature 59-86 degrees F.

Inactive ingredients

Lactose, starch, gelatin with bisulfites and artificial colors.

Questions?

Adverse drug event call: (800) 616-2471

Repacked by:

H.J. Harkins Company, Inc.

Grover Beach, CA 93433

Label

52959-053-10 RX Only: #XXXXXXXX #XXX CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

DIPHENHYDRAMINE 50mg. CAP

Lot #: DIM67M
Mfg: MAJOR
Exp: 01/09 Compare to: Benadryl
Mfg Livonia, MI Mfg. NDC: 0904-5307-80
Loc.: Pill ID: Pink Capsule

Take as directed by your Doctor or
See outsert for usual dosage information

DIPHENHYDRAMINE 50mg. CAP
52959-053-10 Qty #10
01/09 Lot DIM67M
Benadryl 0904-5307-80

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Benadryl 0904-5307-80

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

DIPHENHYDRAMINE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-053(NDC:0904-5307)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine -	Diphenhydramine	50 mg

UNII:8GTS82S83M)	Hydrochloride	50 mg
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Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Lactose (UNII: J2B2A4N98G)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Magnesium Stearate (UNII: 70097M6I30)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	4mm
Flavor		Imprint Code	cpc;836
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-053-06	06 in 1 BOTTLE		
2	NDC:52959-053-12	12 in 1 BOTTLE		
3	NDC:52959-053-15	15 in 1 BOTTLE		
4	NDC:52959-053-20	20 in 1 BOTTLE		
5	NDC:52959-053-10	10 in 1 BOTTLE		
6	NDC:52959-053-30	30 in 1 BOTTLE		
7	NDC:52959-053-52	52 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	08/17/2011	

Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel