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 pharamcist 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.

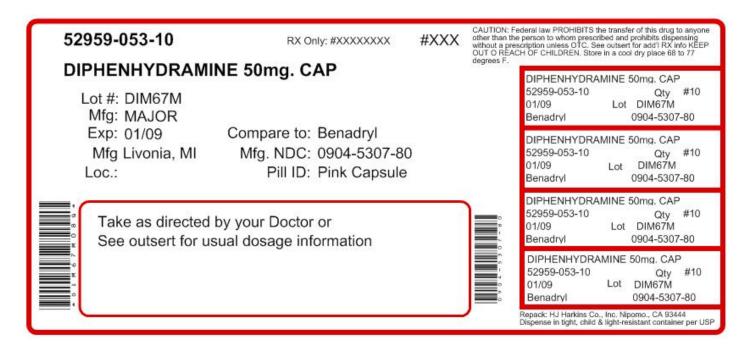
Questions?

Adverse drug event call: (800) 616-2471

Repacked by:

H.J. Harkins Company, Inc. Grover Beach, CA 93433

Label



DIPHENHYDRAMINE

Product Information

diphenhydramine hydrochloride capsule

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

Route	of Ac	lministration		ORAL
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Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine -	Diphenhydramine	50 mg	

UNII:8GTS82S83M) Hydrochloride

Inactive Ingredients			
Ingredient Name	Strength		
Gelatin (UNII: 2G86QN327L)			
Lactose (UNII: J2B2A4N98G)			
Croscarmellose Sodium (UNII: M28 OL 1HH48)			
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	срс;836		
Contains					

P	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

Revised: 4/2012 H.J. Harkins Company, Inc.