DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride capsule
Physicians Total Care, 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.

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine Hydrochloride 25 mg

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies
- runny nose and sneezing
- itching of the nose or throat
- itchy, watery eyes.

Warnings

Ask a doctor before use if you have
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Do not use with ny other product containing diphenhydramine, including products used topically.

Ask a doctor or pharmacist before use if you are
- taking tranquilizers or sedatives
- taking other products containing diphenhydramine

When using this product
- Do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

If pregnant or breastfeeding 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 Center right away.

Directions

- Adults and Children 12 years and over: 25 to 50 mg (1 to 2 capsules) every 4 to 6 hours, not to exceed 12 capsules in 24 hours.
- Children 12 years and under: Consult a Doctor

Inactive ingredients

Colloidal Silicon Dioxide, Corn Starch, D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Anhydrous Lactose, Magnesium Stearate, Silicon Dioxide and Sodium Lauryl Sulfate.

Storage and Handling

Keep tightly closed. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Manufactured for Sandoz Inc.

Princeton, NJ 08540

Manufactured by Epic Pharma, LLC

Laurelton, NY 11413

L1812

Rev. 11/08

Relabeling and Repackaging by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

HOW SUPPLIED

DiphenhydrAMINE Hydrochloride Capsules USP

50 mg

Bottles of 30	NDC 54868-1050-1
Bottles of 100	NDC 54868-1050-5

Package Label - Principal Display Panel

NDC 54868-1050-1

DiphenhydrAMINE

Hydrochloride

Capsules USP

50 mg

30 Capsules

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-1050(NDC:0185-0649)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	PINK (pink top/pink body)	**Score**	no score

Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	E649
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1050-1	30 in 1 BOTTLE		
2	NDC:54868-1050-5	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2000	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel, repack

Revised: 6/2012 Physicians Total Care, Inc.