DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
RedPharm Drug, 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.

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 any 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

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- 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

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

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.

DOSAGE & ADMINISTRATION

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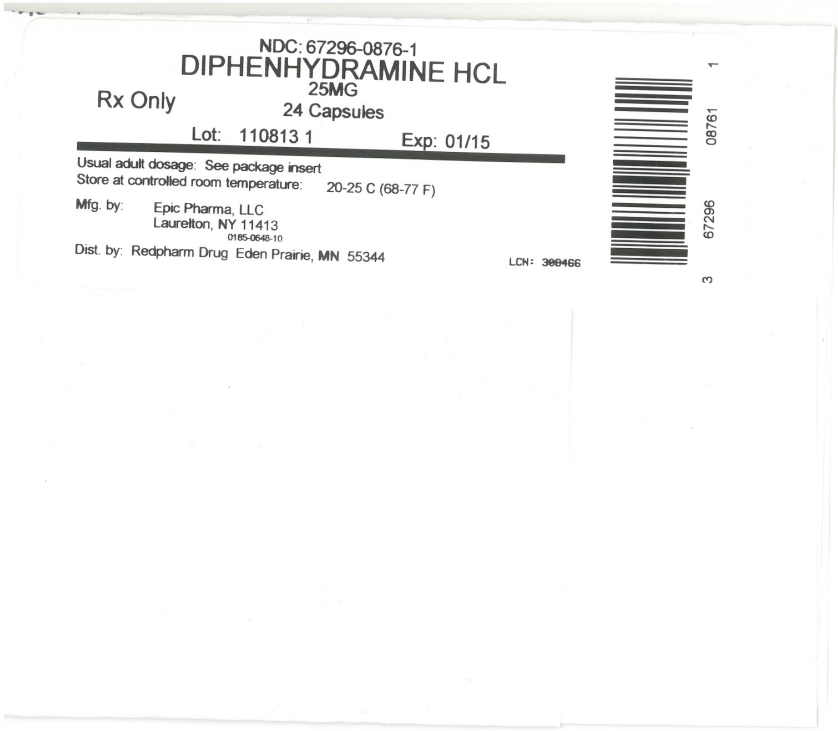
ACTIVE INGREDIENT SECTION

Diphenhydramine Hydrochloride 25 mg

Diphenhydramine Hydrochloride 50 mg

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67296-0876(NDC:0185-0648)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	pink (pink top/clear body)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	E648
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67296-0876-1	24 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2000	

Marketing Information

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

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-0876) , relabel(67296-0876)

Revised: 1/2020 RedPharm Drug, Inc.