

DIPHENHIST- diphenhydramine hcl capsule
Rugby Laboratories

0835-Rugby

Drug Facts

Active ingredient (in each banded capsule)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose ☐
- sneezing ☐
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to the common cold: ☐
- runny nose ☐
- sneezing

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when operating machinery or driving a motor vehicle
- excitability may occur, especially in children

If pregnant of 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: 1-800-222-1222

In case of overdose, get medical help or contact a Poison Control Center right away: **1-800-222-1222**

Directions

- take every 4 to 6 hours □
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	1 to 2 capsules
children 6 to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age

Other information

- store at controlled room temperature 15°-30°C (59°-86°F) in a dry place
- protect from moisture
- contains lactose

Inactive ingredients

D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose and starch.

Questions or comments?

1-800-645-2158

DO NOT USE IF EITHER CAPSULE BAND OR IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by: **Rugby Laboratories**

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

www.rugbylaboratories.com

Rugby

NDC 0536-1010-01

Diphenhist

Diphenhydramine HCl USP, 25 mg

Antihistamine

For the temporary relief of the Symptoms of Upper Respiratory Allergies & Hay Fever

100 Banded Capsules

<p>Questions or comments? (800) 645-2158</p>	
<p>Other information ■ store at room temperature ■ protect from moisture ■ Contains lactose</p>	<p>Inactive ingredients D&C Red #28, FD&C Blue #1, FD&C Red #40, gelatin, lactose, and starch</p>
<p>Directions ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours</p>	<p>When using this product ■ marked drowsiness may occur ■ 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</p>
<p>Warnings Do not use ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin</p>	<p>Drug Facts (continued)</p>
<p>Uses temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat temporarily relieves these symptoms due to the common cold: ■ runny nose ■ sneezing</p>	<p>Directions ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours</p>
<p>Active ingredient Purpose Diphenhydramine HCl 25 mg Antihistamine</p>	<p>Other information ■ store at room temperature ■ protect from moisture ■ Contains lactose</p>
<p>Do not use ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin</p>	<p>When using this product ■ marked drowsiness may occur ■ 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</p>
<p>Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland</p>	<p>Directions ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours</p>
<p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p>	<p>When using this product ■ marked drowsiness may occur ■ 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</p>
<p>Distributed by: Rugby Laboratories 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 www.rugbylaboratories.com</p>	<p>When using this product ■ marked drowsiness may occur ■ 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</p>
<p>Re-order No. 370301</p>	<p>When using this product ■ marked drowsiness may occur ■ 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</p>

DIPHENHIST

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1010
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
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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)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	pink (Half pink and half clear with white powder inside)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;835
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1010-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/17/2014	04/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/17/2014	04/30/2025

Labeler - Rugby Laboratories (079246066)

Revised: 1/2024

Rugby Laboratories