# DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule Proficient Rx LP

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#### **Drug Facts**

### Active ingredient(in each capsule)

Diphenhydramine HCL 50 mg

### **Purpose**

Antihistamine

#### Uses:

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.
- Sneezing.
- Nasal congestion.
- Runny nose.
- Itchy, watery eyes.

## **Warnings:**

#### Do not use

• With any other product containing Diphenhydramine HCL, including one applied topically.

# Ask a doctor or pharmacist before use

If you have

- · Trouble urinating due to enlarged prostate gland
- A breathing problem such as emphysema or chronic bronchitis
- Glaucoma
- If you are taking sedatives or tranquilizers

# When using this product

- · Avoid alcoholic drinks.
- Marked drowsiness may occur.
- Excitability may occur, especially in children.
- Alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery.

#### If pregnant or 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.

#### **Directions:**

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours.

Adults and children 12 years or over	1 capsule
Children under 12 years	ask a doctor

<sup>\*\*25</sup> mg strength is not available in this package. Do not attempt to break capsules.

#### Other information:

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate

# Questions? Adverse drug event call:

1-800-687-0176





NDC 63187-866-30

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

Diphenhydramine HCI 50mg Capsules #30 Lot #:00000 NDC 63187-866-30

SN# MASTER Exp:00/00/00

Diphenhydramine HCI 50mg Capsules SN# MASTER Lot #:00000 Exp:00/00/00 NDC 63187-866-30

Diphenhydramine HCI 50mg Capsules SN#MASTER Exp:00/00/00 NDC 63187-866-30



#30

Lot #:00000

GTIN: 00363187866303 SN# MASTER Exp. 00/00/00 Lot #:00000

# Diphenhydramine HCI 50mg

#30

Capsules

Each capsule contains: Diphenhydramine HCI 50 mg Antihistamine

Pink capsules with imprint code PH013

Product ID: PD086630

Dist By: SDA Laboratories, Inc., Greenwich, CT 06830 MADE IN USA Store at room temperature 15°-30°C (59°-86°F)

Keep medication out of the reach of children

#### DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

#### **Product Information**

**Product Type HUMAN OTC DRUG** Item Code (Source) NDC:63187-866(NDC:66424-021)

**Route of Administration ORAL** 

# **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6|AD40) **DIPHENHYDRAMINE** 50 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE** 

### **Inactive Ingredients Ingredient Name** Strength FERROSOFERRIC OXIDE (UNII: XM0M87F357) **D&C RED NO. 28** (UNII: 767IP0Y5NH) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZB9127XOA) GELATIN, UNSPECIFIED (UNII: 2G86QN327L) LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) MAGNESIUM STEARATE (UNII: 70097M6I30) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) **SODIUM LAURYL SULFATE (UNII: 368GB5141J)**

Product Characteristics				
Color	pink	Score	no score	

Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH013
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187- 866-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2020	
2	NDC:63187- 866-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2017	
3	NDC:63187- 866-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2017	
4	NDC:63187- 866-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/27/2010	

# Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Proficient Rx LP		079196022	REPACK(63187-866)	

Revised: 1/2024 Proficient Rx LP