DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
Proficient Rx LP

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 25 mg

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.

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

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

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 12.5 mg** (1 capsule) every 4 to 6 hours, not more than 6 capsules in 24 hours.

Children under 6 years of age: do not use

**12.5mg dosage strength is not available in this package. Do not attempt to break capsule

Other information

Store at 20º-25ºC (68º-77ºF); excursions permitted to 15º-30ºC (59º-86ºF). [See USP Controlled Room Temperature]. Protect from excessive moisture.

Inactive ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

Questions?

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS

31778 Enterprise Drive

Livonia, MI 48150 USA

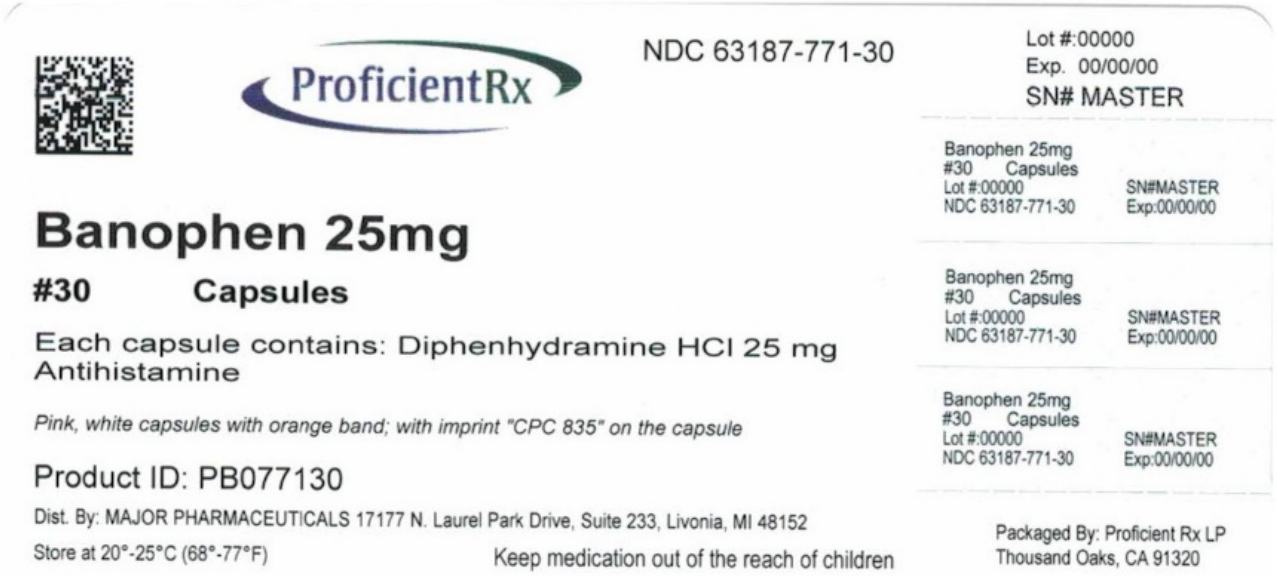
Repackaged by:

Proficient Rx LP

Thousand Oaks, CA 91320

Re-Order No. 301574

PRINCIPAL DISPLAY PANEL DIPHENHYDRAMINE HCL CAPSULES 25MG



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-771(NDC:0904-5306)
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**
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

Product Characteristics			
Color	PINK	**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:63187-771-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2017	
2	NDC:63187-771-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2016	
3	NDC:63187-771-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2016	
4	NDC:63187-771-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/02/2009	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-771)