DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet, coated
Bonita Pharmaceuticals LLC

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 HCL 25mg Caplets

Drug Facts

Active ingredient (in each Caplet)

Diphenhydramine HCl 25 mg

Purposes

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- itching of the nose and throat
- sneezing

Warnings

Do not use

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

Ask a doctor before use if you have

- glaucoma
- difficulty in urinating due to an enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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 effect
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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. (1-800-222-1222)

Directions

- take every 4 to 6 hours as needed
- do not take more than 6 times in 24 hours or as directed by a doctor

Adults and children 12 years and older

- 1 or 2 caplets (25mg to 50mg)

Children under 12years

- ask a doctor

Other Information

- Store at room temperature
- keep lid tightly closed in dry place
- **Do not use if imprinted safety seal under cap is broken or missing**

Inactive Ingredients

Croscarmellose Sodium, D&C Red #27, Dicalcium Phosphate Dihydrate, Hydroxypropyle MethylCellulose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Propylene Glycol, Silica, Stearic Acid and Titanium Dioxide.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (855) 729-7200.

PRINCIPAL DISPLAY PANEL

DIPHENHYDRAMINE HYDROCHLORIDE
diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53598-004
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white ((Coated with pink film))	**Score**	no score
Shape	OVAL ((biconvex))	**Size**	11mm
Flavor		**Imprint Code**	G17
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53598-004-01	100 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph final	part341	05/21/2013	

Labeler - Bonita Pharmaceuticals LLC (004219442)

Registrant - Bonita Pharmaceuticals LLC (004219442)

Establishment

Name	Address	ID/FEI	Business Operations
Bonita Pharmaceuticals LLC		004219442	label(53598-004)

Revised: 5/2013 Bonita Pharmaceuticals LLC