GERI-DRYL ALLERGY RELIEF- diphenhydramine hydrochloride tablet, coated Geri-Care Pharmaceutical Corp

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.

Active ingredient (in each tablet)

Diphenhydramine Hydrochloride 25mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever and other upper respiratory allergies:
 - -runny nose
 - -sneezing
 - -itching of the nose and throat
 - -itchy, watery eyes

Warnings

Do not use • to make a child sleepy • with any other product containing diphenhydramine, including one used on skin

Ask a doctor before use if you have • a breathing problem such as chronic bronchitis or emphysema • trouble urinating due to an enlarged prostate gland • glaucoma

Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers

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

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

- do not exceed recommended dose
- adults and children 12 years and over, take 1 to 2 tablets every 4-6 hours, as needed; not more than 12 tablets in 24 hours, or as directed by a doctor
- children under 12 years: consult a doctor

Other information

- each tablet contains: calcium 25mg
- store at room temperature 15°C 30°C (59°F 86°F)
- for institutional use only

Inactive ingredients

cellulose, croscarmellose sodium, D and C red #27 lake, dicalcium phosphate, hypromellose, magnesium stearate, PEG, polysorbate 80, silica, titanium dioxide, wax.

package label

New! Ultra Small Tablets NDC 57896-681-01

GERICARE
GERI-DRYL
(ALLERGY RELIEF)
Diphenhydramine HCl
Antihistamine
Compare to active ingredient in Benadryl Ultratabs
PACKAGE NOT CHILD RESISTANT
100 Tablets
25 mg each



GERI-DRYL ALLERGY RELIEF

diphenhydramine hcl tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:57896-681	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX	

SILICON DIO XIDE	
CROSCARMELLOSE SODIUM	
D&C RED NO. 27	
HYPROMELLOSES	
CELLULO SE, MICRO CRYSTALLINE	
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE	
MAGNESIUM STEARATE	
POLYETHYLENE GLYCOL 400	
POLYSORBATE 80	
TITANIUM DIO XIDE	

Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	T;061	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:57896-681-01	100 in 1 BOTTLE			
2	NDC:57896-681-10	1000 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	09/01/2011	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Establishment				
Name	Address	ID/FEI	Business Operations	
Geri-Care Pharmaceutical Corp		611196254	repack(57896-681)	

Revised: 12/2012 Geri-Care Pharmaceutical Corp