

ALLERGY ANTIHISTAMINE - diphenhydramine hydrochloride tablet
Select Corporation

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.

Drug Facts

Active Ingredients

Diphenhydramine HCl 25 mg

Antihistamine

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 caplets • Children 6 to under 12 years of age: 1 caplet • children under 6 years of age: do not use this product in children under 6 years of age

Uses: • temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itchy 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 driving a motor vehicle or operating machinery • excitability may occur, especially in children.

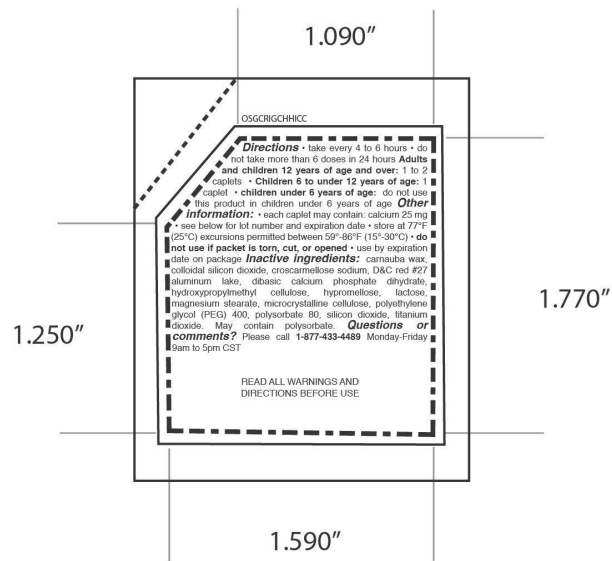
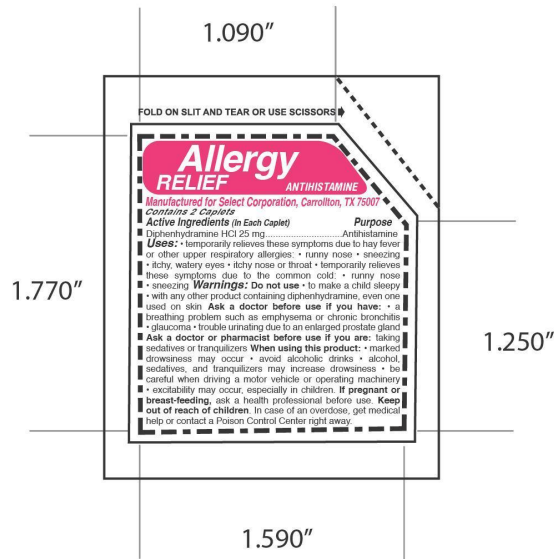
If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

Inactive ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, DC red 27 aluminum lake, dibasic calcium phosphate dihydrate, hydroxypropylmethyl cellulose, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, silicon dioxide, titanium dioxide

MM1

Allergy Relief - Antihistamine



diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-460
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE (UNII: J2B2A4N98G)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	pink (rose pink)	Score	no score
Shape	CAPSULE (T;061)	Size	11mm
Flavor		Imprint Code	T;061
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-460-02	2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2012	

Labeler - Select Corporation (053805599)

