BENALDRYL - diphenhydramine hcl tablet
AJES 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.

Drug Facts

Active Ingredient (in each tablet)

Diphenhydramine HCI USP 25 mg

Purpose

Antihistamine

Keep out of the reach of children

In case of accidental overdose,

seek professional assistance or contact a Poison Control Center

Uses

-temporarily relieves these symptoms due to hay fever or upper

respiratory allergies: runny nose - sneezing - itchy, watery eyes

-itching of the nose and 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

Directions - take every 4 to 6 hours

-do not take more than 6 doses in 24 hours

adults and children 12 years of age or older - 1 to 2 tablets

children 6 years to under 12 years of age - 1 tablet

children under 6 years of age - do not use this product in children under 6 years of age

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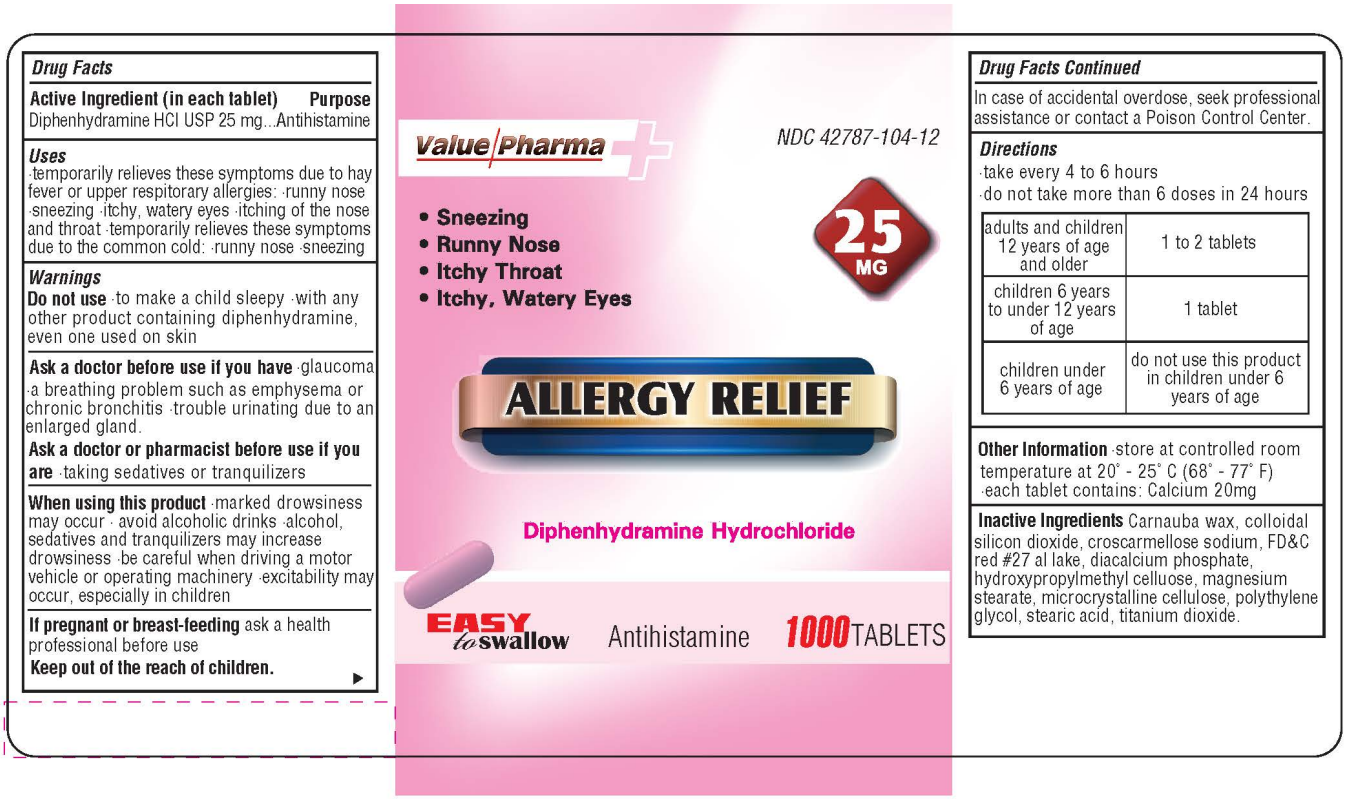

BENALDRYL

diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42787-104
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 in 250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink (pink)	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	C22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42787-104-12	1 in 1 CARTON		
1		25000 mg in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2012	

Labeler - AJES PHARMACEUTICALS,LLC (159945393)

Establishment

Name	Address	ID/FEI	Business Operations
AJES PHARMACEUTICALS,LLC		159945393	manufacture(42787-104) , repack(42787-104) , relabel(42787-104)

Revised: 5/2014 AJES PHARMACEUTICALS,LLC