

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 HCl 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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Active Ingredient (in each tablet)	Purpose
Diphenhydramine HCl USP 25 mg...	Antihistamine
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	
Ask a doctor before use if you have glaucoma -a breathing problem such as emphysema or chronic bronchitis -trouble urinating due to an enlarged 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 the reach of children.	

Value/Pharma  NDC 42787-104-12

- Sneezing
- Runny Nose
- Itchy Throat
- Itchy, Watery Eyes

25 MG

ALLERGY RELIEF

Diphenhydramine Hydrochloride

EASY to swallow Antihistamine **1000 TABLETS**

Drug Facts Continued	
In case of accidental overdose, seek professional assistance or contact a Poison Control Center.	
Directions	
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adults and children 12 years of age and 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
Other Information -store at controlled room temperature at 20° - 25° C (68° - 77° F)	
-each tablet contains: Calcium 20mg	
Inactive Ingredients Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #27 al lake, diacalcium phosphate, hydroxypropylmethyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, stearic acid, titanium dioxide.	

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: 3WJQ0SDW1A)	
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