BENADRYL ALLERGY- diphenhydramine hydrochloride tablet, coated
Rebel Distributors 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.

Benadryl® ™
ALLERGY

Drug Facts

Active ingredient (in each gelcap)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

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

- glaucoma
- trouble urinating due to an enlarged 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
- 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. In case of overdose, get medical help or contact a Poison Control

Center right away. (1-800-222-1222)

Directions

- if needed, repeat dose every 4 to 6 hours
- do not take more than 6 times in 24 hours

adults and children 12 years of age and over	1 to 2 gelcaps
children 6 to under 12 years of age	1 gelcap
children under 6 years of age	do not use this product in children under 6 years of age

Other information

- each gelcap contains: **calcium 35 mg**
- store between 20-25°C (68-77°F). Avoid high humidity.
- **do not use if carton is open or if blister unit is broken**
- see side panel for lot number and expiration date

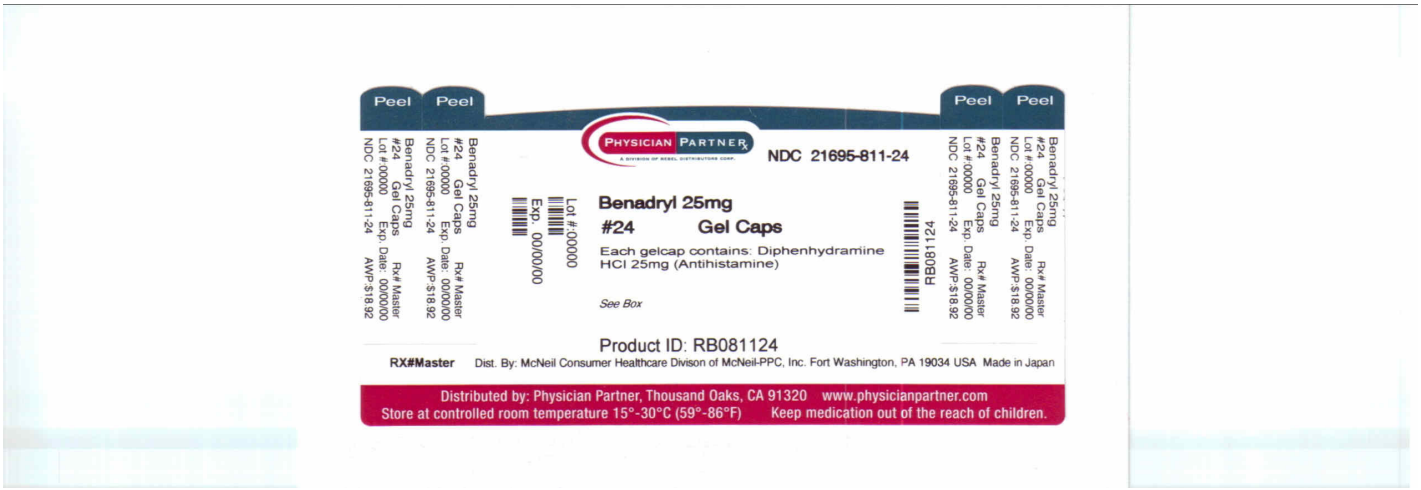
Inactive ingredients

benzyl alcohol, black iron oxide, butylparaben, carboxymethylcellulose sodium, crospovidone, D&C red #28, dibasic calcium phosphate dihydrate, edetate calcium disodium, FD&C red #40, gelatin, hypromellose, magnesium stearate, methylparaben, microcrystalline cellulose, polyethylene glycol, polysorbate 80, propylparaben, red iron oxide, sodium lauryl sulfate, sodium propionate, titanium dioxide, yellow iron oxide

Questions or comments?

call 1-877-717-2824

PRINCIPAL DISPLAY PANEL



BENADRYL ALLERGY

diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-811(NDC:50580-580)
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**
butylparaben (UNII: 3QPI1U3FV8)	

Product Characteristics			
Color	PINK, WHITE (with gray subcoat band)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	Ben;A
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:21695-811-24	3 in 1 CARTON		
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 4/2011 Rebel Distributors Corp