ALLERGY RELIEF ANTIHISTAMINE- diphenhydramine hydrochloride tablet
Mckesson (Sunmark)

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 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 of 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 operating machinery or driving a motor vehicle
- excitability may occur, especially in children

If pregnant of 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

- take every 4 to 6 hours
- do not more than 6 doses in 24 hours

adults and children 12 years of age and over	1 to 2 tablets
children 6 to under 12 years of age	1 tablet
children under 6 years of age	do not use this product in children under 6
children under 4 years of age	**do not use**

Other information

- each tablet contains: **calcium 25mg/ tablet**
- store at room temperature 15°-30°C (59°-86°F)
- protect from light and moisture
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Red #27 Aluminum Lake, dibasic calcium phosphate dihydrate, hypromellose, *lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, *polyvinyl alcohol, *purified water, *talc, and titanium dioxide

* Contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

Allergy Relief

Antihistamine

For the temporary relief of:

sneezing, itchy & watery eyes, runny nose & itchy throat

Diphenhydramine HCl 25 mg

Compare to Benadryl® Allergy ultratab® Active Ingredient*

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Benadryl® Allergy Ultratab®

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

Product Label

Diphenhydramine HCl 25 mg

ALLERGY RELIEF ANTIHISTAMINE

diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:49348-983
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX	
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
D&C RED NO. 27	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE	
HYPROMELLOSES	
EGG PHOSPHOLIPIDS	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL 400	
POLYSORBATE 80	
POLYVINYL ALCOHOL	
WATER	
TALC	
TITANIUM DIOXIDE	

Product Characteristics

Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	T;61;V;25;S4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-983-04	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:49348-983-10	1 in 1 BOX		
2		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	09/28/2011	

Labeler - Mckesson (Sunmark) (177667227)