BENADRYL ALLERGY ULTRATAB- diphenhydramine hydrochloride tablet, film coated
Savings Distributors 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.

Benadryl Allergy Ultratab

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 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.

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, or as directed by a doctor

■ do not take more than 6 times in 24 hours

adults and children 12 years and over 1 to 2 tablets

children 6 to under 12 years 1 tablet

children under 6 years do not use

Other information

■ **each tablet contains:** calcium 15 mg

■ store between 20-25°C (68-77°F). Protect from light.

■ **do not use if pouch is torn or damaged**

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C red no. 27 aluminum lake, dibasic calcium phosphate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

call **1-877-717-2824** (toll-free) or **215-273-8755** (collect)

Package Label

BENADRYL ALLERGY ULTRATAB

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73097-004(NDC:50580-226)
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	

ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	B;WL;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73097-004-50	25 in 1 CARTON	07/03/2019	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:73097-004-40	20 in 1 CARTON	07/03/2019	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:73097-004-02	1 in 1 CARTON	07/03/2019	
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/03/2019	

Labeler - Savings Distributors LLC (010527359)

Revised: 7/2019 Savings Distributors LLC