BENADRYL ULTRATABS- diphenhydramine hydrochloride tablet, film coated Navajo Manufacturing Company Inc.

Benadryl Ultratabs

Drug Facts

Active ingredient (in each caplet)

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 20 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 Labeling:



BENADRYL ULTRATABS

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67751-166(NDC:50580-226)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)
(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

25 mg

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-166- 01	1 in 1 CARTON	09/22/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-166- 02	1 in 1 CARTON	09/22/2016	
2		4 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	• • • • • • • • • • • • • • • • • • • •		Marketing End Date
OTC Monograph Drug	M012	09/22/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment				
Name	Address	ID/FEI	Business Operations	
Navajo Manufacturing Company Inc.		136941411	relabel(67751-166), repack(67751-166)	

Revised: 10/2024 Navajo Manufacturing Company Inc.