BENADRYL- diphenhydramine hydrochloride tablet, film coated Kenvue Brands LLC

Benadryl ®

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 blister unit is torn or broken

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)

PRINCIPAL DISPLAY PANEL

NDC 50580-226-12

Benadryl[®]

ALLERGY

Diphenhydramine HCl 25mg | Antihistamine

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

ULTRATABS ®*

*small tablet size actual size

12 TABLETS



BENADRYL

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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:50580- 226-50	1 in 1 CARTON	06/04/2012		
1		100 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:50580- 226-51	2 in 1 CARTON	06/04/2012		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:50580- 226-53	2 in 1 POUCH; Type 0: Not a Combination Product	06/04/2012		
4	NDC:50580- 226-54	60 in 1 CARTON	07/27/2015		
4		2 in 1 POUCH; Type 0: Not a Combination Product			
5	NDC:50580- 226-62	4 in 1 CARTON	01/02/2017		
5		2 in 1 POUCH; Type 0: Not a Combination Product			
6	NDC:50580- 226-52	4 in 1 CARTON	06/04/2012		
6		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
7	NDC:50580- 226-56	3 in 1 PACKAGE	02/01/2013		
7		4 in 1 CARTON			
7		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
8	NDC:50580- 226-20	2 in 1 CARTON	01/15/2024		
8		1 in 1 CARTON			
8		100 in 1 BOTTLE; Type 0: Not a Combination Product			
9	NDC:50580- 226-70	1 in 1 CARTON	06/02/2025		
9		48 in 1 BOTTLE; Type 0: Not a Combination Product			

226-12	1 in 1 CARTON	06/11/2025	
10	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Dru	m M012	09/01/2008	

Labeler - Kenvue Brands LLC (118772437)

Revised: 4/2025 Kenvue Brands LLC