

BENADRYL- diphenhydramine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

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 carton is opened or if blister unit is 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 50580-226-51

Benadryl®

ALLERGY

Diphenhydramine HCl 25mg | Antihistamine

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



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)	
CROSCARMELOSE 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/01/2008	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 12/2023

Johnson & Johnson Consumer Inc.