

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

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[®]

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**

ULTRATABS®*

*small tablet size

actual size

24 TABLETS



Benadryl[®] ALLERGY

Important: Read all product information before using. Keep this box for important information.

Drug Facts
Active ingredient (in each tablet)
 Diphenhydramine HCl 25 mg.....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
 ■ trouble urinating due to an enlarged prostate gland
 ■ glaucoma
 Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
 ■ marked drowsiness may occur
 ■ avoid alcoholic drinks
 When using this product
 ■ 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
 carnuba 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)

Benadryl[®] ALLERGY

CHILD-RESISTANT
PACKAGING

Active ingredient made in Japan
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19084 USA
 ©J&JCI 2016

Benadryl[®] ALLERGY

EFFECTIVE ALLERGY RELIEF WHEN YOU NEED IT![®]

NDC 50580-226-51

Benadryl[®]

ALLERGY

Diphenhydramine HCl 25mg | Antihistamine

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



30037905



30037905



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 (UNII: 2LRS185U6K)	
Aluminum Oxide (UNII: LMI26O6933)	
Dibasic Calcium Phosphate Dihydrate (UNII: O7TSZ97GEP)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OPIR32D61U)	
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	NDC:50580-226-52	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 final	part341	09/01/2008	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 6/2018

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division