# BENADRYL- diphenhydramine hydrochloride tablet, film coated Morning Star OTC

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**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)

Repackaged by:

# **Morning Star OTC**

145 S. Anderson St, Los Angeles,

CA 90033

#### PRINCIPAL DISPLAY PANEL-2 Tablets



#### PRINCIPAL DISPLAY PANEL-2 Tablets x 25 Packets



# BENADRYL diphenhydramine hydrochloride tablet, film coated Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:53209-3001(NDC:50580-226)

**Route of Administration** 

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
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: 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	Item Code Package Description		Marketing End Date
1	NDC:53209- 3001-2	25 in 1 PACKET	06/09/2025	
1	NDC:53209- 3001-1	2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/09/2025	

# Labeler - Morning Star OTC (078589357)

Establishment				
Name	Address	ID/FEI	Business Operations	
Morning Star OTC		078589357	repack(53209-3001)	

Revised: 6/2025 Morning Star OTC