LEADER ALLERGY - diphenhydramine hydrochloride tablet
Cardinal Health

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.

Cardinal Health Allergy Tablets 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

- 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
- difficulty in urination due to an enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when operating machinery or driving a motor vehicle

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.

Directions

- take every 4 to 6 hours, not more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 or 2 tablets
children 6 to under 12 years of age	take 1 tablet
children under 6 years of age	consult a doctor
children under 4 years of age	**do not use**

Other information

- each tablet contains: **calcium 25 mg/tablet**
- store at room temperature 15°-30°C (59°-86°F)
- protect from light and moisture

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, DandC Red 27Aluminum Lake, dibasic calcium phosphate dihydrate, hypromellose, lecithin*, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, polyvinyl alcohol*, purified water*, talc*, and titanium dioxide

* contains one or more of these ingredients

Questions or comments?

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Benadryl Allergy Ultratabs.

Package/Label Principal Display Panel

NDC 63548-0070-1

*Compare to the active ingredient in Benadryl® Allergy Ultratabs®

Antihistamine

Allergy Tablets

Diphenhydramine Hydrochloride 25 mg

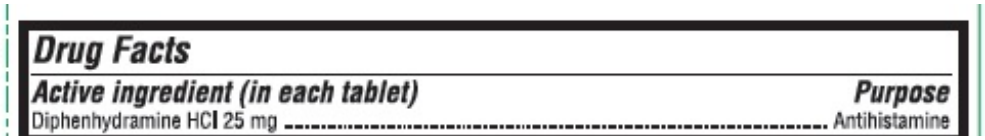
For Allergy Relief

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

12 Tablets

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION



Uses ■ temporarily relieves these symptoms of the common cold: ■ runny nose ■ sneezing ■ temporarily relieves symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy nose or throat ■ itchy, watery eyes

Warnings

Do not use 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 ■ difficulty in urination due to an enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product ■ excitability may occur especially in children ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ use caution when operating machinery or driving a motor vehicle

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.

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Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Red #27 Aluminum Lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80 and titanium dioxide. May also contain: polyvinyl alcohol and talc.

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Allergy Tablets

Diphenhydramine HCl 25 mg

Antihistamine

SATISFACTION GUARANTEED

24 TABLETS

NDC 37205-270-62

LEADER®

Compare to Benadryl® Allergy Ultratabs® active ingredient*

Allergy Tablets

Diphenhydramine HCl 25 mg

Antihistamine

For Allergy Relief

• Runny Nose • Sneezing

• Itchy Throat • Itchy, Watery Eyes

SATISFACTION GUARANTEED

24 TABLETS

LEADER ALLERGY

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-270
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	PINK (dark)	**Score**	no score
Shape	CAPSULE	**Size**	10mm
Flavor		**Imprint Code**	T61;V25;EL
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37205-270-62	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:37205-270-78	1 in 1 CARTON		
2		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/11/1992	

Labeler - Cardinal Health (097537435)

Revised: 6/2012 Cardinal Health