

ALLERGY RELIEF- diphenhydramine hcl tablet, film coated
Cardinal Health 110, LLC. DBA Leader

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.

Leader 44-329

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
 - itchy, watery eyes
 - sneezing
 - 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
- difficulty in urination due to enlargement of the 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 beverages

- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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.

Directions

- **do not take more than directed**
- 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 30 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- protect from moisture
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

LEADER™

NDC 70000-0136-1

Allergy Relief

Diphenhydramine HCl, 25 mg | Antihistamine

Allergy Relief For:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat

24 MINI TABLETS

Actual Size

COMPARE TO BENADRYL® ALLERGY ULTRATAB® active ingredient*

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by Johnson & Johnson Corporation,
owner of the registered trademark Benadryl® Allergy ULTRATAB®.

50844 REV0721C32908

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DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

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LEADER™

Allergy Relief

Diphenhydramine HCl, 25 mg | Antihistamine

LEADER™

NDC 70000-0136-1

Allergy Relief

Diphenhydramine HCl, 25 mg | Antihistamine

LEADER™

Allergy Relief
Diphenhydramine HCl, 25 mg | Antihistamine

Allergy Relief For:

Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat



Actual Size

24 MINI TABLETS

COMPARE TO
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active ingredient*

100% Money Back Guarantee

no print / no varnish area
lot no. & exp. date

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BILISTER
UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

CIN 5283650 REV. 10/21
0 96295 12934 2

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B-0225-329-08
REV0721C32908

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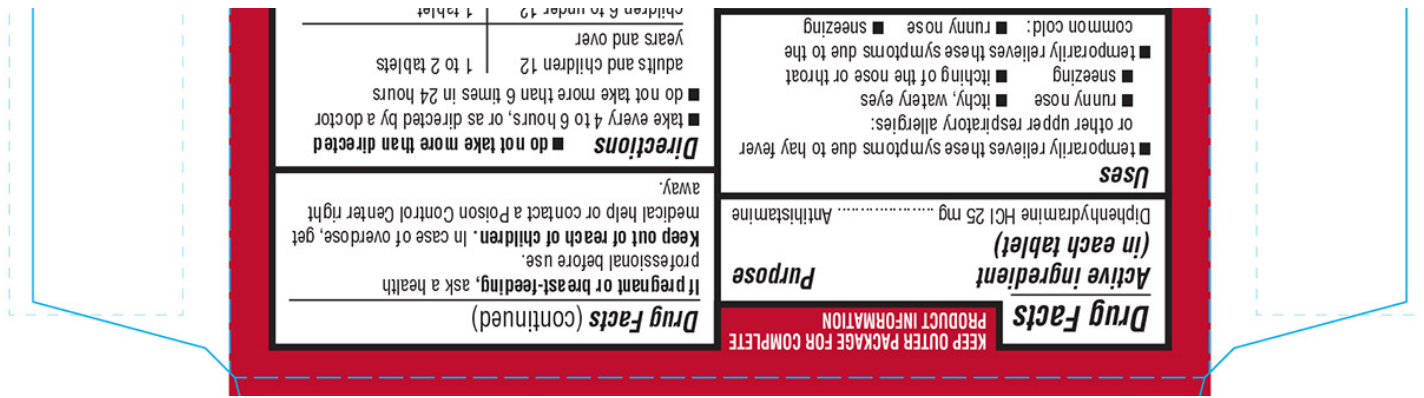
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Leader 44-329

ALLERGY RELIEF

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0136
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	44;329
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0136-2	4 in 1 CARTON	03/02/1990	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0136-3	1 in 1 CARTON	03/02/1990	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70000-0136-1	2 in 1 CARTON	03/02/1990	
3		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	03/02/1990	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0136)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(70000-0136)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0136)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70000-0136) , pack(70000-0136)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0136)