

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
Akron Pharma Inc.

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.

Akron Pharma, Inc.

Active ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 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

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

- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

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 (1-800-222-1222) right away.

Directions

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

Age	Dose
adults and children 12 years and over	1 to 2 capsules
children 6 to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age

Other information

- store at temperature 15° to 30° C (59° to 86°F)
- do not use if either capsule band or imprinted safety seal under cap is broken or missing
- protect from moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hard gelatin capsules, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, propyl paraben sodium.

Questions or comments?

Call toll-free 1-877-225-6999
Mfg Lic .No: TN/DRUGS/558/1997

Manufactured for:
Akron Pharma, Inc,
373 RT US 46 W, Building E,
Suite 117, Fairfield, NJ 07004

Akron Pharma NDC 71399-8026-1

*Compare to active ingredient in BENADRYL® Allergy

Diphenhydramine HCl Capsules

50 mg

Antihistamine

Complete Allergy Medication

For the temporary relief of the symptoms of
•Upper Respiratory Allergies •Hay Fever

100 CAPSULES

Drug Facts

Active ingredient (in each labeled capsule)
Diphenhydramine Hydrochloride 50 mg Antihistamine

Uses

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

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

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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)

Child-Resistant Packaging **Drug Facts** (continued under label)

*This Product is not manufactured or distributed by Johnson & Johnson consumer inc, owner of the registered trademark Benadryl.®

Batch No. :
Mfg. Date :
Exp. Date :

PEEL HERE FOR MORE DRUG FACTS

Akron Pharma
Manufactured for:
Akron Pharma, Inc.
373 RT US 46 W Building E,
Suite 117, Fairfield, NJ 07004
www.akronpharma.com

Drug Facts (continued)

Directions ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 capsule (50 mg)
children under 12 years of age	ask a doctor, the proper dosage strength is not available in this package**

** Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

Other information

- store at temperature 15° to 30° C (59° to 86°F) ■ do not use if either capsule band or imprinted safety seal under cap is broken or missing
- protect from moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hard gelatin capsules hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, propyl paraben sodium.

Questions or comments? Call toll-free 1-877-225-6999

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275/MHC/CS/101

DIPHENHYDRAMINE HCL			
diphenhydramine hcl capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-8026
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
GELATIN (UNII: 2G86QN327L)			

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

Product Characteristics

Color	pink (light pink)	Score	no score
Shape	capsule	Size	18mm
Flavor		Imprint Code	AP;26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8026-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2021	
2	NDC:71399-8026-2	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	01/15/2021	

Labeler - Akron Pharma Inc. (067878881)

Revised: 2/2023

Akron Pharma Inc.