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.

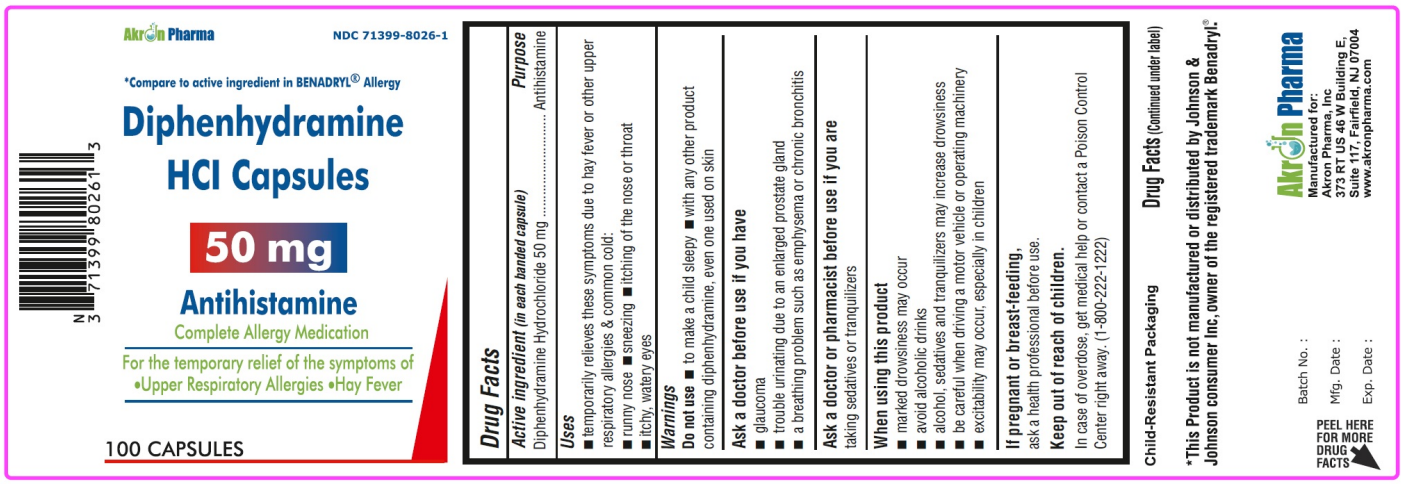
Questions or comments?

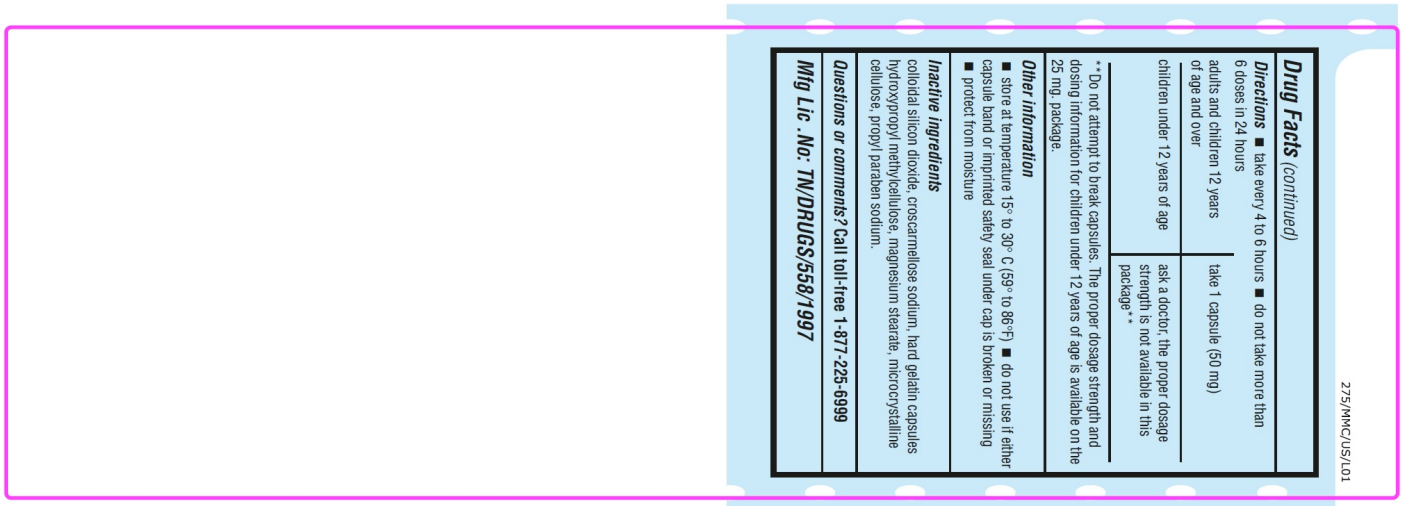
Call toll-free 1-877-225-6999
Mfg Lic .No: TN/DRUGS/558/1997

Manufactured for:
Akron Pharma, Inc,

373 RT US 46 W, Building E,

Suite 117, Fairfield, NJ 07004





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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GELATIN (UNII: 2G86QN327L)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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.