DIPHENHYDRAMINE- diphenhydramine hydrochloride capsule
PURINEPHARMA LLC

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.

DIPHENHYDRAMINE HCl CAPSULES

Active Ingredient (each banded capsule contains)
Diphenhydramine HCL 50 mg

Purpose
Antihistaminne

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

Ask a doctor before use if you have

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

Do not use to make a child sleepy

Do not use with any other product containing diphenhydramine, even one used on skin

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.

Directions:

- Take every 4 to 6 hours.
- Do not take more than 6 doses in any 24-hour period.

Adults and Children 12 years of age 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

Other information

- Store between 15-30 degree Celsius (59-86 degree Fahrenheit)

- Protect from moisture

D&C red 28, gelatin, lactose monohydrate, magnesium stearate, maize starch, polysorbate tween 80, silica gel.

Pack Size: 50 Capsules in a Bottle
Batch No.:
Mfg. Date:
Exp. Date:

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING.

NDC 58599-004-90
NDC 58599-004-25
NDC 58599-004-29
NDC 58599-004-35

Manufactured By: **PURINEPHARMA LLC**
5 County Route 42
Massena, NY – 13662
www.purinepharma.com

Medibest Allergy Relief Diphenhydramine – 50 mg / Antihistamine LABEL **BULK – 50 mg**

Recommended Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
1) runny nose 2) sneezing 3) itchy, watery eyes
4) itching of the nose or throat
Temporarily relieves these symptoms due to the common cold:
4) runny nose 2) sneezing

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	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

Ingredients

Active Ingredients:
(in each banded capsule): Diphenhydramine HCl (50 mg)
Inactive Ingredients:
Maize Starch, Lactose Monohydrate, Magnesium Stearate, Gelatin, Polysorbate 80, D&C Red 28, Empty hard Gelatin Cap size "4" (Pink/Pink)

Other Information

- Store at 59° to 77°F in a dry place
- Protect from moisture
- Keep out of reach of children.
- In case of overdose, get medical help or contact a Poison Control Center right away.

NDC# 58599-004-90

Medibest

ALLERGY RELIEF
DIPHENHYDRAMINE HCl – 50 mg / Antihistamine

Easy to Swallow

Relieves

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

Medibest Logo

PURINEPHARMA LLC
5 County Route 42
Massena, NY – 13662
www.purinepharma.com

Natural

*Each Capsule individually banded for your protection

*Fast acting Anti histamine

Warning

Do not use:
- To make a child sleepy
- With any other product containing diphenhydramine, even one used on skin.

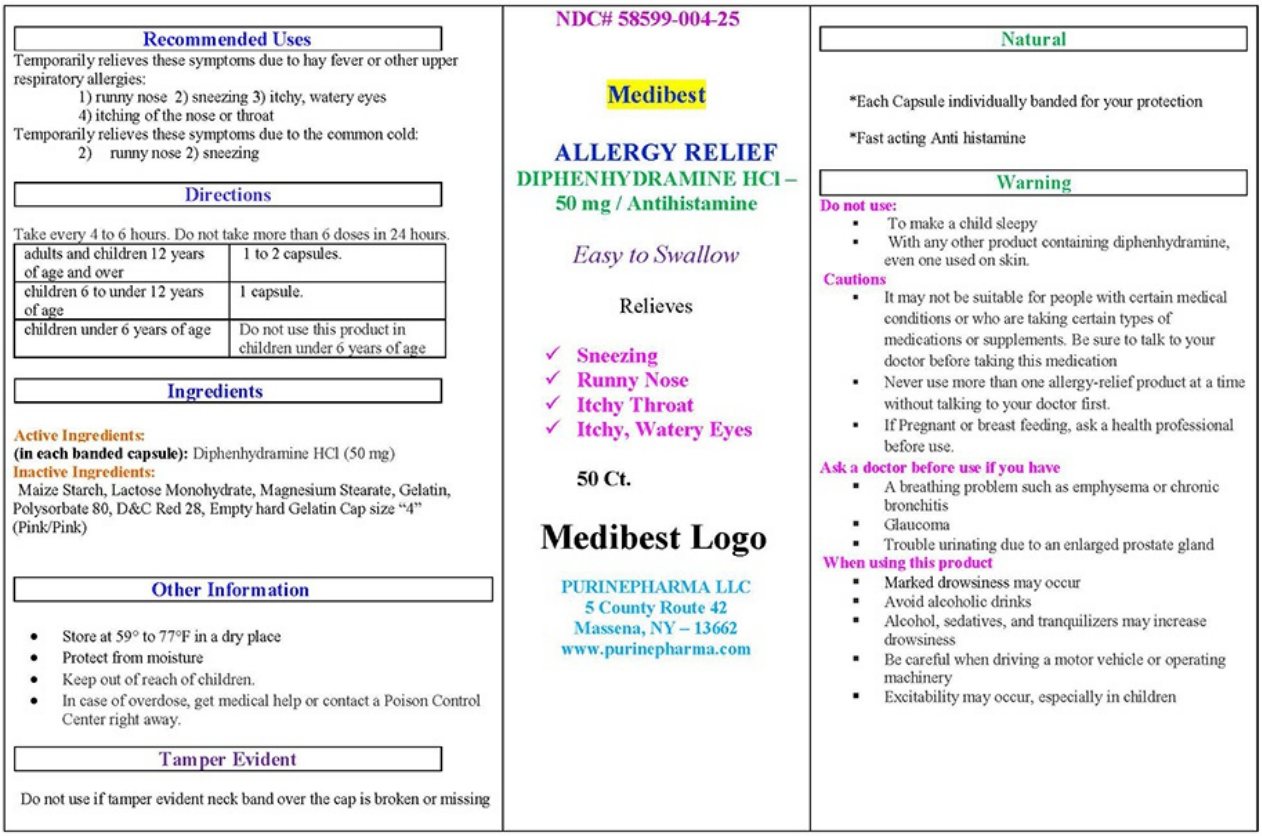
Cautions
- It may not be suitable for people with certain medical conditions or who are taking certain types of medications or supplements. Be sure to talk to your doctor before taking this medication
- Never use more than one allergy-relief product at a time without talking to your doctor first.
- If Pregnant or breast feeding, ask a health professional before use.

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

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

Total Qty: 50,000 Caps/ Box

Medibest Allergy Relief Diphenhydramine – 50 mg / Antihistamine LABEL **50 ct – 50 mg**



Recommended Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

1) runny nose 2) sneezing 3) itchy, watery eyes
4) itching of the nose or throat

Temporarily relieves these symptoms due to the common cold:

2) runny nose 2) sneezing

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	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

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Other Information

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- Protect from moisture
- Keep out of reach of children.
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Tamper Evident

Do not use if tamper evident neck band over the cap is broken or missing

NDC# 58599-004-25

Medibest

ALLERGY RELIEF
DIPHENHYDRAMINE HCl – 50 mg / Antihistamine

Easy to Swallow

Relieves

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

50 Ct.

Medibest Logo

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DIPHENHYDRAMINE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58599-004
Route of Administration	ORAL, Type 0: Not a Combination Product		

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
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics			
Color	PINK (PINK CAP and PINK BODY)	**Score**	2 pieces
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	DH;50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58599-004-90	50000 in 1 BOX		
2	NDC:58599-004-25	1 in 1 CARTON		
2		50 in 1 BOTTLE		
3	NDC:58599-004-29	1 in 1 CARTON		
3		100 in 1 BOTTLE		
4	NDC:58599-004-35	1 in 1 CARTON		
4		1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2014	

Labeler - PURINEPHARMA LLC (019950491)

Registrant - PURINEPHARMA LLC (019950491)

Establishment

Name	Address	ID/FEI	Business Operations
PURINEPHARMA LLC		019950491	manufacture(58599-004)

Revised: 8/2014 PURINEPHARMA LLC