

**PREFERRED PLUS COMPLETE ALLERGY MEDICINE - diphenhydramine hydrochloride capsule**

**Kinray 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.*

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**Drug Facts**

**Active ingredient (in each banded capsule)**

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**

- Glaucoma
- A breathing problem such as emphysema or chronic bronchitis
- Trouble urinating due to an enlarged 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 drinks
- 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 the reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take every 4 to 6 hours
- do not exceed 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	ask a doctor

**Other information**

- Store at controlled room temperature 15<sup>0</sup>-30<sup>0</sup>C (59<sup>0</sup>-86<sup>0</sup>F)
- Protect from excessive moisture

**Inactive ingredients**

D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate

**Questions?**

**Adverse drug event call:** (866) 562-2756

**Principal Display Panel**

**Complete Allergy Medicine**

Antihistamine

Diphenhydramine HCl 25mg

For the temporary relief of:

- itchy, watery eyes
- runny nose,
- itchy throat
- sneezing

Blocks Histamine

\*Compare to the Active Ingredient in Benadryl®.

Safety Sealed Capsules

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl®. All Preferred Plus Pharmacy are satisfaction guaranteed or your money back from retailer where purchased.

**Distributed By: Kinray, Inc.**

**Whitestone, NY 11357**

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## Product Label

Complete Allergy Medication capsule safety system has been designed with the following key feature:



Application of a safety band where the two capsule halves meet. This process seals the two halves into one secure unit.

Each safety sealed capsule is encased in a plastic blister with a foil back. Do not use if blister or foil is broken. Do not use if red safety band is broken or missing.

Child-resistant Packaging

NDC 61715-055-24



# Complete Allergy Medicine

Antihistamine  
Diphenhydramine HCl 25mg.

For the temporary relief of:

- itchy, watery eyes
- itchy throat



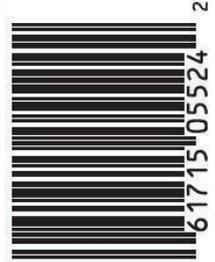
- runny nose
- sneezing

Blocks Histamine

24 Safety Sealed Capsules



\*Compare to the Active Ingredient in Benadryl®



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Complete Allergy Medicine

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LRev 03/13  
KIN 320-994

## Complete Allergy Medicine

**Tamper Evident:** do not use if carton is opened or if blister unit is torn, broken or shows any signs of tampering. Use by expiration date on package.

<b>Purpose</b>	Diphenhydramine HCl 25 mg ..... Antihistamine
<b>Uses</b>	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.
<b>Warnings</b>	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, trouble urinating due to an enlarged 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 drinks. 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 the reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Do not exceed 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: ask a doctor.
<b>Directions</b>	Take every 4 to 6 hours. Do not exceed 6 doses in 24 hours.
<b>Other information</b>	Store at controlled room temperature 15°-30°C (59°-86°F). Protect from moisture.
<b>Inactive ingredients</b>	D&C red #28, edible ink, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate.
<b>Questions? Adverse drug event call:</b>	(866) 562-2756

## PREFERRED PLUS COMPLETE ALLERGY MEDICINE

diphenhydramine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-055
<b>Route of Administration</b>	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
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	PH;014
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-055-51	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		
2	NDC:61715-055-24	2 in 1 CARTON		
2		12 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part341	05/07/2013	
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**Labeler** - Kinray Inc. (012574513)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

**Establishment**

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(61715-055) , pack(61715-055) , label(61715-055)

Revised: 5/2013

Kinray Inc.