

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule**  
**Lake Erie Medical DBA Quality Care Products 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.*

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**DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25mg**

**Drug Facts**

**Active Ingredient**

**(in each capsule)**

Diphenhydramine HCl 25 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

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

**WARNINGS**

**Do not use** 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**

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives & 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**

- **adults and children 12 years and over:** take 1 to 2 capsules every 4-6 hours; not more than 6 doses

in 24 hours

- **children under 12 years: ask a doctor**

### Other Information

- store at 15-30 °C (59-86 °F)
- protect from moisture
- For 1000 Count: This is a bulk package. Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP

### Inactive Ingredients

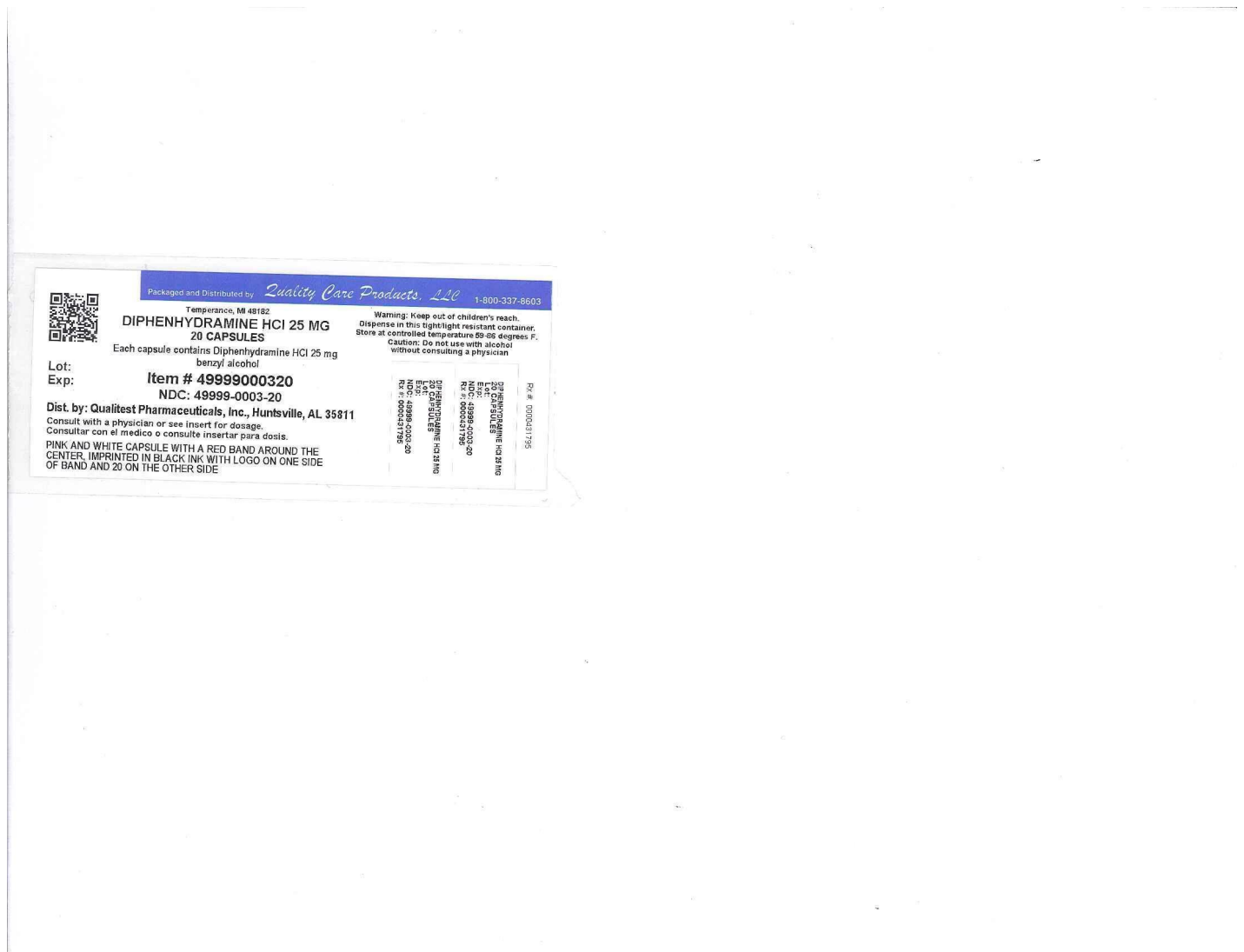
benzyl alcohol, butylparaben, D&C red# 28, edible black ink, FD&C blue #1, FD&C red# 40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium laurel sulfate

### Questions or Comments

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED**

**Distributed by: Qualitest Pharmaceuticals, Inc.**

### Image of Label



# DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49999-003(NDC:0603-3339)
<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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
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>	AP;020
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49999-003-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	
2	NDC:49999-003-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	01/01/2012
3	NDC:49999-003-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	01/01/2012
4	NDC:49999-003-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	
5	NDC:49999-003-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	01/01/2012
6	NDC:49999-003-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/24/2007	

**Labeler** - Lake Erie Medical DBA Quality Care Products LLC (831276758)

## Establishment

Name	Address	ID/FEI	Business Operations
Lake Erie Medical DBA Quality Care Products LLC		831276758	repack(49999-003)

Revised: 3/2017

Lake Erie Medical DBA Quality Care Products LLC