# 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**

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#### **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 bule #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				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49999- 003(NDC:0603-3339)	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL			
BUTYLPARABEN			
D&C RED NO. 28			

FD&C BLUE NO. 1	
FD&C RED NO. 40	
GELATIN	
LACTOSE	
MAGNESIUM STEARATE	
METHYLPARABEN	
POLYSORBATE 80	
PROPYLPARABEN	
SO DIUM LAURYL SULFATE	

Product Characteristics			
Color	PINK	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;020
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49999-003-20	20 in 1 BOTTLE				
2	NDC:49999-003-21	21 in 1 BOTTLE				
3	NDC:49999-003-24	24 in 1 BOTTLE				
4	NDC:49999-003-30	30 in 1 BOTTLE				
5	NDC:49999-003-60	60 in 1 BOTTLE				
6	NDC:49999-003-15	15 in 1 BOTTLE				

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	<b>Business Operations</b>
Lake Erie Medical DBA Quality Care Products LLC		831276758	repack(49999-003)

Revised: 7/2013 Lake Erie Medical DBA Quality Care Products LLC