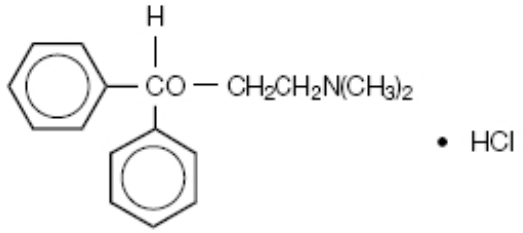
DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
Contract Pharmacy Services-PA

Diphenhydramine Hydrochloride Capsules, USP

Rx only

DESCRIPTION:

Diphenhydramine Hydrochloride is an antihistamine drug having the chemical name 2-(diphenylmethoxy)-*N*, *N*-dimethylethylamine hydrochloride. It occurs as a white, odorless crystalline powder and is freely soluble in water and alcohol. The structural formula is as follows:



$C_{17}H_{21}NO$ • HCl Molecular Weight: 291.82

Each capsule contains 50 mg of diphenhydramine hydrochloride for oral administration.

Inactive Ingredients:

Anhydrous lactose, lactose monohydrate and magnesium stearate.

The 50 mg capsule shell contains D&C red no. 28, FD&C blue no. 1, FD&C red no. 40, gelatin, silicon dioxide and sodium lauryl sulfate.

The imprinting ink contains D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, pharmaceutical glaze, propylene glycol and synthetic black iron oxide.

CLINICAL PHARMACOLOGY:

Diphenhydramine hydrochloride is an antihistamine with anticholinergic (drying) and sedative effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

A single oral dose of diphenhydramine hydrochloride is quickly absorbed with maximum activity occurring in approximately one hour. The duration of activity following an average dose of diphenhydramine hydrochloride is from four to six hours. Diphenhydramine is widely distributed throughout the body, including the CNS. Little, if any, is excreted unchanged in the urine; most appears as the degradation products of metabolic transformation in the liver, which are almost completely excreted within 24 hours.

INDICATIONS AND USAGE:

Diphenhydramine hydrochloride in the oral form is effective for the following indications:

Antihistaminic:

For allergic conjunctivitis due to foods; mild, uncomplicated allergic skin manifestations of urticaria

and angioedema; amelioration of allergic reactions to blood or plasma; dermatographism; as therapy for anaphylactic reactions *adjunctive* to epinephrine and other standard measures after the acute manifestations have been controlled.

Motion Sickness:

For active and prophylactic treatment of motion sickness.

Antiparkinsonism:

For parkinsonism (including drug-induced) in the elderly unable to tolerate more potent agents; mild cases of parkinsonism (including drug-induced) in other age groups; in other cases of parkinsonism (including drug-induced) in combination with centrally acting anticholinergic agents.

Nighttime sleep-aid.

CONTRAINDICATIONS:

Use in Newborn or Premature Infants:

This drug should *not* be used in newborn or premature infants.

Use in Nursing Mothers:

Because of the higher risk of antihistamines for infants generally, and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Antihistamines are also contraindicated in the following conditions: Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

WARNINGS:

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Use in Children:

In infants and children, especially, antihistamines in overdosage may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

Use in Elderly (approximately 60 years or older):

Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

PRECAUTIONS:

General:

Diphenhydramine hydrochloride has an atropine-like action and therefore should be used with caution in patients with a history of lower respiratory disease including asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension.

Information for Patients:

Patients taking diphenhydramine hydrochloride should be advised that this drug may cause drowsiness

and has an additive effect with alcohol.

Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Drug Interactions:

Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc).

MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.

Pregnancy:

Pregnancy Category B:

Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

ADVERSE REACTIONS:

The most frequent adverse reactions are underscored.

1. *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
2. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.
5. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses.
7. *Respiratory System:* Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

Overdosage:

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms, dry mouth; fixed, dilated pupils; flushing; and gastrointestinal symptoms may also occur.

If vomiting has not occurred spontaneously the patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

If vomiting is unsuccessful gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or (½) isotonic saline is the lavage solution of choice.

Saline cathartics, as milk of magnesia, by osmosis draw water into the bowel and therefore are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used.

Vasopressors may be used to treat hypotension.

DOSAGE AND ADMINISTRATION:

DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND RESPONSE OF THE PATIENT.

A single oral dose of diphenhydramine hydrochloride is quickly absorbed with maximum activity occurring in approximately one hour. The duration of activity following an average dose of diphenhydramine hydrochloride is from four to six hours.

ADULTS:

25 to 50 mg three or four times daily. The nighttime sleep-aid dosage is 50 mg at bedtime.

CHILDREN:

(over 20 lb): 12.5 to 25 mg three to four times daily. Maximum daily dosage not to exceed 300 mg. For physicians who wish to calculate the dose on the basis of body weight or surface area, the recommended dosage is 5 mg/kg/24 hours or 150 mg/m^2/24 hours.

Data are not available on the use of diphenhydramine hydrochloride as a nighttime sleep-aid in children under 12 years.

The basis for determining the most effective dosage regimen will be the response of the patient to medication and the condition under treatment.

In motion sickness, full dosage is recommended for prophylactic use, the first dose to be given 30 minutes before exposure to motion and similar doses before meals and upon retiring for the duration of exposure.

HOW SUPPLIED:

Diphenhydramine Hydrochloride Capsules, USP are supplied by **Contract Pharmacy Services-PA** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
67046-127-30	50 mg	30 Capsules in a Blister Pack	PINK	0555-0059

Store at controlled room temperature 15°-30°C (59°-86°F).

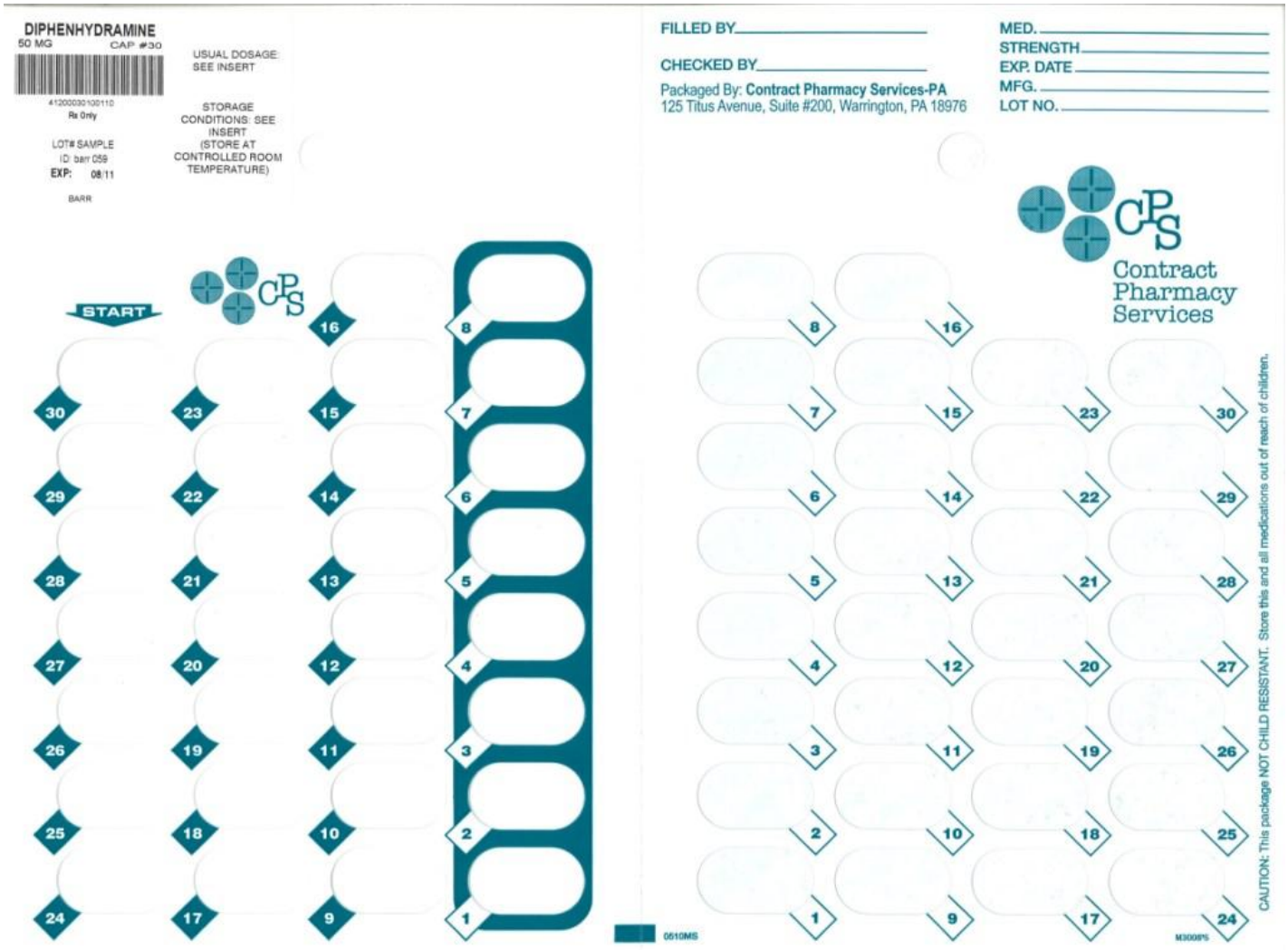
MANUFACTURED BY
BARR LABORATORIES, INC.
POMONA, NY 10970

Repackaged by:

Contract Pharmacy Services-PA
125 Titus Ave Suite 200
Warrington, PA 18976 USA

Original--08/2010--NJW

Label Image 50 mg



50 mg Capsules

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67046-127(NDC:0555-0059)
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**

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	barr;059
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-127-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080738	08/05/2010	

Labeler - Contract Pharmacy Services-PA (945429777)

Revised: 8/2010 Contract Pharmacy Services-PA