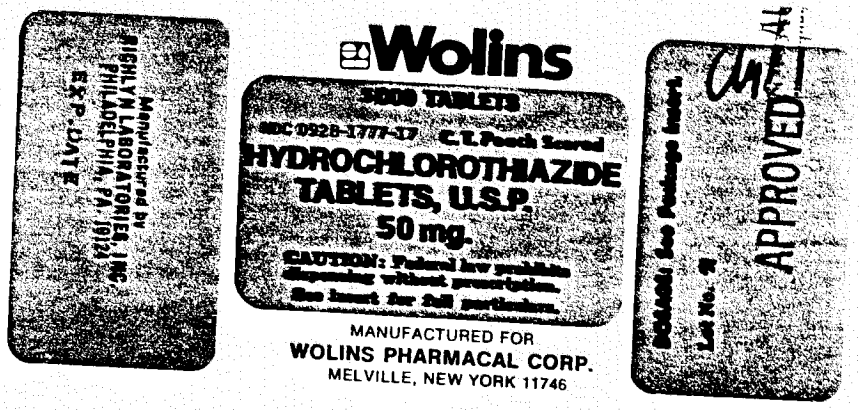
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83607

PRINTED LABELING


Manufactured by
HIGHLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124
EXP. DATE
Wolins
3000 TABLETS
NDC 0928-1777-37 C.T. Pouch 3 card
HYDROCHLOROTHIAZIDE
TABLETS, U.S.P.
50 mg.
CAUTION: Federal law prohibits
dispensing without prescription.
See insert for full particulars.
MANUFACTURED FOR
WOLINS PHARMACAL CORP.
MELVILLE, NEW YORK 11746
APPROVED

NDC 0537-2332-01

100 TABLETS C.T. Peach Scored

HYDROCHLOROTHIAZIDE

TABLETS, U.S.P.

50 mg.

CAUTION: Federal law prohibits dispensing without prescription.

See insert for full particulars.

Mfd. by
BROOKLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124

EXP. DATE

APPROVED

DOSAGE: See package insert.

Lot No. R

SM MANUFACTURED FOR SPENCER-MEAD INC. VALLEY STREAM, N.Y. 11582

NDC 0537-2332-10

1000 TABLETS C.T. Peach Scored

HYDROCHLOROTHIAZIDE

TABLETS, U.S.P.

50 mg.

CAUTION: Federal law prohibits dispensing without prescription.

See insert for full particulars.

Mfd. by
BROOKLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124

EXP. DATE

APPROVED

DOSAGE: See package insert.

Lot No. R

SM MANUFACTURED FOR SPENCER-MEAD INC. VALLEY STREAM, N.Y. 11582

STAR IDE BRAND

NDC 0814-3725-14

100 TABLETS C.T. Peach Scored

HYDROCHLOROTHIAZIDE

TABLETS, U.S.P.

50 mg.

CAUTION: Federal law prohibits dispensing without prescription.
See insert for full particulars.

Manufactured for
INTERSTATE DRUG EXCHANGE, INC.
PLAINVIEW, L.I., N.Y. 11803

APPROVED AUG

DOSAGE: See Package Insert.

Lot No. 69

Mfd by
RICHLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124

EXP. DATE

NDC 0814-3725-30

1000 TABLETS C.T. Peach Scored

HYDROCHLOROTHIAZIDE

TABLETS, U.S.P.

50 mg.

CAUTION: Federal law prohibits dispensing without prescription.
See insert for full particulars.

Manufactured for
INTERSTATE DRUG EXCHANGE, INC.
PLAINVIEW, L.I., N.Y. 11803

APPROVED AUG 1

DOSAGE: See Package Insert.

Lot No. R 69

EXP. DATE

Manufactured by
RICHLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124

Manufactured by

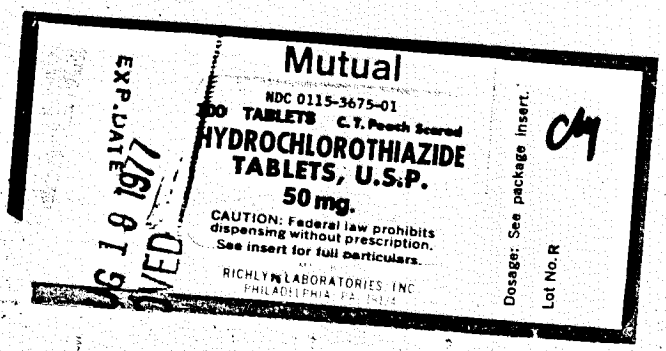
RICHLYN LABORATORIES, INC.

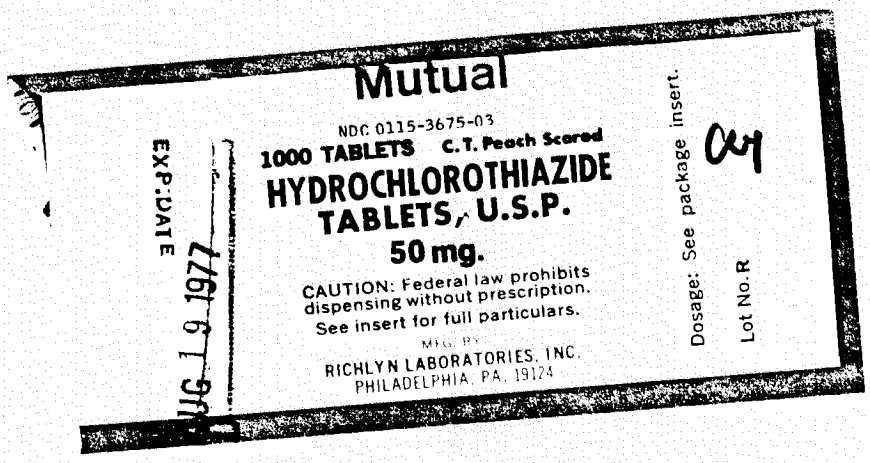
Philadelphia, PA 19124

EXP. DATE

DOSAGE: See Package Insert.

Lot No.


Mutual
NDC 0115-3675-01
100 TABLETS C.T. Peach Scored
HYDROCHLOROTHIAZIDE
TABLETS, U.S.P.
50 mg.
CAUTION: Federal law prohibits dispensing without prescription.
See insert for full particulars.
RICHLYN LABORATORIES, INC
Dosage: See package insert.
Lot No.R
EXP. DATE
OCT 10 1977
VED


Mutual
NDC 0115-3675-03
1000 TABLETS C.T. Peach Scored
HYDROCHLOROTHIAZIDE
TABLETS, U.S.P.
50 mg.
CAUTION: Federal law prohibits dispensing without prescription.
See insert for full particulars.
MFG. BY
RICHLYN LABORATORIES, INC.
PHILADELPHIA, PA. 19124
Dosage: See package insert.
Lot No.R
EXP. DATE
OCT 6 1977

HYDROCHLOROTHIAZIDE TABLETS

DESCRIPTION: Hydrochlorothiazide is the 3,4-dihydro derivative of chlorothiazide. Its chemical name is 6-chloro-7-sulfamyl-3, 4-dihydro-1,2,4-benzothiadiazine-1,1-dioxide. It is a white, or practically white, crystalline powder with low solubility in water, but is readily soluble in dilute aqueous sodium hydroxide.

ACTIONS: Thiazides affect the renal tubular mechanism of electrolyte re-absorption. At maximal therapeutic dosage all thiazides are approximately equal in their diuretic potency.
Thiazides increase excretion of sodium and chloride in approximately equivalent amounts. Natriuresis causes a secondary loss of potassium and bicarbonate. The mechanism of the antihypertensive effect of thiazides is unknown. Thiazides do not affect normal blood pressure.
Onset of action of thiazides occurs in 2 hours and the peak effect at about 4 hours. The action persists for approximately 6 to 12 hours. Thiazides are eliminated rapidly by the kidney.

INDICATIONS: Hydrochlorothiazide is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis and corticosteroid and estrogen therapy.
Hydrochlorothiazide has also been found useful in edema due to various forms of renal dysfunction as: nephrotic syndrome; acute glomerulonephritis; and chronic renal failure.
Hydrochlorothiazide is indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of hypertension.
Usage in Pregnancy: The routine use of diuretics in an otherwise healthy woman is inappropriate and exposes mother and fetus to unnecessary hazard. Diuretics do not prevent development of toxemia of pregnancy, and there is no satisfactory evidence that they are useful in the treatment of developed toxemia. Edema during pregnancy may arise from pathological causes or from the physiologic and mechanical consequences of pregnancy. Thiazides are indicated in pregnancy when edema is due to pathologic causes, just as they are in the absence of pregnancy (however, see WARNINGS below). Dependent edema in pregnancy, resulting from restriction of venous return by the expanded uterus, is properly treated through elevation of the lower extremities and use of support hose; use of diuretics to lower intravascular volume in this case is illogical and unnecessary. There is hypervolemia during normal pregnancy which is harmful to neither the fetus nor the mother (in the absence of cardiovascular disease), but which is associated with edema, including generalized edema, in the majority of pregnant women. If this edema produces discomfort, increased recumbency will often provide relief. In rare instances, this edema may cause extreme discomfort which is not relieved by rest. In these cases, a short course of diuretics may provide relief and may be appropriate.

CONTRAINDICATIONS: Anuria.
Hypersensitivity to this or other sulfonamide-derived drugs.

WARNINGS: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.
Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.
Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic blocking drugs.
Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.
The possibility of exacerabation or activation of systemic lupus erythematosus has been reported.
Usage in Pregnancy: Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnant women requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.
Nursing Mothers: Thiazides appear in breast milk. If the use of the drug is deemed essential, the patient should stop nursing.

PRECAUTIONS: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.
All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause are: dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.
Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of the drug may be enhanced in the post-sympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathological changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

ADVERSE REACTIONS:

A. GASTROINTESTINAL SYSTEM

1. anorexia
2. gastric irritation
3. nausea
4. vomiting
5. cramping
6. diarrhea
7. constipation
8. jaundice (intrahepatic cholestatic jaundice)
9. pancreatitis
10. sialadenitis

B. CENTRAL NERVOUS SYSTEM

1. dizziness
2. vertigo
3. paresthesias
4. headache
5. xanthopsia

C. HEMATOLOGIC

1. leukopenia
2. agranulocytosis
3. thrombocytopenia
4. aplastic anemia

D. CARDIOVASCULAR

1. Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

E. HYPERSENSITIVITY

1. purpura
2. photosensitivity
3. rash
4. urticaria
5. necrotizing angiitis (vasculitis) (cutaneous vasculitis)
6. fever
7. respiratory distress including pneumonitis
8. anaphylactic reactions

F. OTHER

1. hyperglycemia
2. glycosuria
3. hyperuricemia
4. muscle spasm
5. weakness
6. restlessness
7. transient blurred vision

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

DOSAGE AND ADMINISTRATION: Therapy should be individualized according to patient response. This therapy should be titrated to gain maximal therapeutic response as well as the minimal dose possible to maintain that therapeutic response.

The usual daily dosages for antihypertensive and diuretic effect are roughly comparable as well as the oral and parenteral dosages.

ADULTS

DIURETIC USE:
25 to 100 mg. once or twice a day.

ANTIHYPERTENSIVE USE:
25 to 50 mg. once or twice a day.

PEDIATRIC

Usual dosage is based on 1 mg./lb./day, given as 2 doses.

(Note: Infants under 6 months of age may require up to 1.5 mg./lb./day, given as 2 doses.)

CAUTION: Federal law prohibits dispensing without prescription.

HOW SUPPLIED: Each scored, peach, compressed tablet contains the label-stated dose (25 mg. or 50 mg. or 100 mg.) of hydrochlorothiazide.

AUGUST, 1976