RENESE- polythiazide tablet
Pfizer Labs

RENESE®

(polythiazide)

TABLETS

for Oral Administration

DESCRIPTION

Renese® is designated generically as polythiazide, and chemically as 2*H*-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-3,4-dihydro-2-methyl-3-[[(2,2,2-trifluoroethyl)thio]methyl]-, 1,1-dioxide. It is a white crystalline substance, insoluble in water but readily soluble in alkaline solution.

Inert Ingredients: dibasic calcium phosphate; lactose; magnesium stearate; polyethylene glycol; sodium lauryl sulfate; starch; vanillin. The 2 mg tablets also contain: Yellow 6; Yellow 10.

ACTION

The mechanism of action results in an interference with the renal tubular mechanism of electrolyte reabsorption. At maximal therapeutic dosage all thiazides are approximately equal in their diuretic potency. The mechanism whereby thiazides function in the control of hypertension is unknown.

INDICATIONS

Renese is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

Renese has also been found useful in edema due to various forms of renal dysfunction as: Nephrotic syndrome; Acute glomerulonephritis; and Chronic renal failure.

Renese 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 exacerbation 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 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 with thiazides as with any other potent diuretic, 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. Digitalis therapy may exaggerate metabolic effects of hypokalemia especially with reference to myocardial activity.

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 in 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. Latent diabetes

mellitus 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 postsympathectomy 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, as indicated by a rising nonprotein nitrogen or blood urea nitrogen, a careful reappraisal of therapy is necessary with consideration given to withholding or discontinuing diuretic therapy.

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

A. GASTROINTESTINAL SYSTEM REACTIONS

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

B. CENTRAL NERVOUS SYSTEM REACTIONS

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

C. HEMATOLOGIC REACTIONS

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

D. DERMATOLOGIC—HYPERSENSITIVITY REACTIONS

1. purpura
2. photosensitivity
3. rash
4. urticaria
5. necrotizing angiitis

   (vasculitis)

   (cutaneous vasculitis)

E. CARDIOVASCULAR REACTION

Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics.

F. OTHER

1. hyperglycemia
2. glycosuria
3. hyperuricemia
4. muscle spasm
5. weakness
6. restlessness

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 dosage of Renese tablets for diuretic therapy is 1 to 4 mg daily, and for antihypertensive therapy is 2 to 4 mg daily.

HOW SUPPLIED

RENESE (polythiazide) Tablets are available as:

1 mg white, scored tablets in bottles of 100 (NDC 0069-3750-66).

2 mg yellow, scored tablets in bottles of 100 (NDC 0069-3760-66).

4 mg white, scored tablets in bottles of 100 (NDC 0069-3770-66).

Rx Only

69-1116-00-6

April 1997

RENESE
polythiazide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0069-3750
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
polythiazide (UNII: 36780APV5N) (polythiazide - UNII:36780APV5N)		1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
dibasic calcium phosphate ()	
lactose ()	
magnesium stearate ()	
polyethylene glycol ()	
sodium lauryl sulfate ()	
starch ()	
vanillin ()	

Product Characteristics			
Color	WHITE (White)	**Score**	2 pieces
Shape	ROUND (Round)	**Size**	7mm
Flavor		**Imprint Code**	Pfizer;375
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0069-3750-66	100 in BOTTLE		

RENESE

polythiazide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0069-3760
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
polythiazide (UNII: 36780APV5N) (polythiazide - UNII:36780APV5N)		2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
dibasic calcium phosphate ()	
lactose ()	

magnesium stearate ()	
polyethylene glycol ()	
sodium lauryl sulfate ()	
starch ()	
vanillin ()	
yellow 6 ()	
yellow 10 ()	

Product Characteristics			
Color	YELLOW (Yellow)	**Score**	2 pieces
Shape	ROUND (Round)	**Size**	9mm
Flavor		**Imprint Code**	Pfizer;376
Contains			
Coating	false	**Symbol**	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-3760-66	100 in BOTTLE		

RENESE

polythiazide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0069-3770
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
polythiazide (UNII: 36780APV5N) (polythiazide - UNII:36780APV5N)		4 mg

Inactive Ingredients

Ingredient Name	Strength
dibasic calcium phosphate ()	
lactose ()	
magnesium stearate ()	
polyethylene glycol ()	
sodium lauryl sulfate ()	
starch ()	
vanillin ()	

Product Characteristics

Color	WHITE (White)	**Score**	2 pieces
Shape	ROUND (Round)	**Size**	9mm
Flavor		**Imprint Code**	Pfizer;377
Contains			
Coating	false	**Symbol**	false

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-3770-66	100 in BOTTLE		

Labeler - Pfizer Labs

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