

GOLDSHIELD

DYAZIDE®

DESCRIPTION

Each round peach-colored, scored, compressed tablet contains 50 mg of triamterene and 25 mg of hydrochlorothiazide.

ACTIONS

'DYAZIDE' is a diuretic/antihypertensive drug product that combines two natriuretics, each of which complement the action of the other. The hydrochlorothiazide component blocks the reabsorption of sodium and chloride ions and thereby increases the quantity of sodium traversing the distal tubule and the volume of water excreted. A portion of the additional sodium presented to the distal tubule is exchanged there for potassium and hydrogen ions. With continued use of hydrochlorothiazide and depletion of sodium, compensatory mechanisms tend to increase this exchange and may produce excessive loss of potassium and hydrogen ions.

The triamterene component of 'DYAZIDE' exerts its diuretic effect on the distal renal tubule to inhibit the reabsorption of sodium in exchange for potassium and hydrogen ions. By inhibiting the distal tubular exchange mechanism, triamterene maintains or increases the sodium excretion and reduces the excess loss of potassium and hydrogen ions induced by hydrochlorothiazide.

The duration of diuretic activity and effective dosage range of the hydrochlorothiazide and triamterene components of 'DYAZIDE' are similar.

INDICATIONS

'DYAZIDE' is indicated in the treatment of mild to moderate hypertension when the potassium-sparing action of triamterene is warranted (thiazide-like diuretics may lower serum potassium levels) and in those patients in whom potassium depletion is considered likely to occur or is especially dangerous (e.g. digitalized patients). It can be used alone or in combination with other antihypertensive drugs.

'DYAZIDE' is indicated in the treatment of edema associated with congestive heart failure, hepatic cirrhosis and the nephrotic syndrome; also in corticosteroid and estrogen induced edema.

CONTRAINDICATIONS

Progressive renal dysfunction, including anuria, increasing oliguria and increasing azotemia; development of hyperkalemia while on 'DYAZIDE'; pre-existing elevated serum potassium, as is sometimes seen in patients with impaired renal function. Increasing hepatic dysfunction in patients on 'DYAZIDE'. Hypersensitivity to either drug in the preparation or to other sulfonamide-derived drugs.

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PRECAUTIONS

Patients should not be placed on dietary potassium supplements or potassium salts in conjunction with 'DYAZIDE' therapy, unless they develop hypokalemia or their dietary intake of potassium is markedly impaired. Because of potassium conserving effect of the triamterene component, hypokalemia is an uncommon occurrence with the use of 'DYAZIDE'. Should it develop--during prolonged therapy with high dosages or in patients with salt restricted diet-- corrective measures should then be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Discontinue corrective measures immediately if laboratory determinations reveal an abnormal elevation of serum potassium. Substitute a thiazide diuretic alone until potassium levels return to normal.

Abnormal elevation of serum potassium, although uncommon, is potentially the most severe electrolyte disturbance with 'DYAZIDE' therapy. Hyperkalemia has been reported to be associated with cardiac irregularities. Accordingly, periodic potassium determination should be performed during the therapy. This is particularly important in the treatment of patients with suspected or confirmed renal insufficiency, such as elderly or diabetic patients. In patients who develop hyperkalemia, 'DYAZIDE' should be withdrawn and a thiazide alone substituted.

Electrolyte imbalance, often encountered in such diseases as heart failure, renal disease or cirrhosis of the liver, may also be aggravated by diuretics and should be considered during 'DYAZIDE' therapy when using high doses for prolonged periods or in patients on a salt- restricted diet. Periodic serum electrolyte determinations are recommended during therapy.

'DYAZIDE' 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.

'DYAZIDE' may produce an elevated blood urea nitrogen level, creatinine level or both. This apparently is secondary to a reversible reduction of glomerular filtration rate or a depletion of intravascular fluid volume, rather than renal toxicity. If azotemia increase, discontinue 'DYAZIDE'.

Thiazide may cause hyperglycemia and glycosuria and alter insulin requirements in diabetes. Hyperuricemia may be observed with possible occurrence of gout. 'DYAZIDE' may have similar effects. Triamterene may cause a decreasing alkali reserve with the possibility of metabolic acidosis.

Rare cases of blood dyscrasias have been reported in patients receiving triamterene. Leucopenia, thrombocytopenia, agranulocytosis and aplastic anemia have been reported with the thiazides. It is recommended that patients treated with 'DYAZIDE' be observed regularly for the possible occurrence of blood dyscrasias. Triamterene has been reported, in higher doses, to increase the incidence of renal stones.

Drug Interactions

Lithium generally should not be given with diuretics because they reduce its renal clearance and increase the risk of lithium toxicity.

'DYAZIDE' should not be given to patients receiving other potassium-sparing agents. Angiotensin-converting enzyme (ACE) inhibitors can also elevate serum potassium levels; the co- administration of these agents with 'DYAZIDE' should be undertaken with caution.

A possible interaction resulting in acute renal failure has been reported in a few patients on 'DYAZIDE' when treated with indomethacin and therefore, particular care should be exercised in patients receiving non-steroidal anti-inflammatory drugs and potassium-sparing agents like triamterene.

Concurrent use with chlorpropamide may increase the risk of severe hyponatremia.

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 thrombocytopenia or pancreatitis (see ADVERSE REACTIONS).

Nursing Mothers

Thiazides appear and triamterene may appear in breast milk. If use of the drug product is deemed essential, the patient should stop nursing.

Usage in Children

Adequate information on the use of 'DYAZIDE' in children is not available.

ADVERSE REACTIONS

Adverse reactions observed in association with the use of 'DYAZIDE' include muscle cramps, weakness, dizziness, headache and dry mouth; anaphylaxis, rash, urticaria, photosensitivity and purpura; nausea and vomiting, diarrhea and constipation; arrhythmia and postural hypotension.

It should be noted that nausea and vomiting can also be indicative of electrolyte imbalance.

Rare incidents of acute interstitial nephritis have been reported with the use of 'DYAZIDE', although a causal relationship has not been established.

Newborns, whose mothers had received thiazides during pregnancy, have developed thrombocytopenia or pancreatitis in rare instances.

DOSAGE AND ADMINISTRATION

The treatment of hypertension and edema is not static, but must be re-evaluated as conditions in each patient warrant.

In hypertension, the usual initial adult dose is one tablet per day, increasing to two tablets if necessary, to control blood pressure. For edema, the usual initial adult dose is one or two tablets twice daily after meals. Some patients may be maintained on one tablet daily or every other day.

The maximum daily dosage should not exceed four tablets, at this dosage the incidence of adverse events may increase.

Hypotensive drugs used concomitantly with 'DYAZIDE' should be added at reduced dosage - one half the usual dosage--particularly if it is a ganglionic blocking agent. Adjust dosage as indicated. Adequate information on the use of 'DYAZIDE' in children is not available.

OVERDOSAGE

Electrolyte imbalance is the major concern. Symptoms reported include polyuria, nausea, vomiting, weakness, lassitude, fever, flushed face and hyperactive deep tendon reflexes. If hypotension occurs, it may be treated with pressor agents such as levarterenol to maintain blood pressure. Carefully, evaluate the electrolyte pattern and fluid balance. Induce immediate evacuation of the stomach through emesis or gastric lavage. There is no specific antidote.