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TRIAMIZIDE

Hydrochlorothiazide; triamterene



Presentation

Peach flat bevel edged tablet, 11/32" (8.7 mm) diameter, imprinted T50/H25 on one side. Each tablet contains hydrochlorothiazide 25mg and triamterene 50mg.

Uses

Actions

TRIAMIZIDE 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 TRIAMIZIDE 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.

Pharmacokinetics

The duration of diuretic activity and effective dosage range of the hydrochlorothiazide and triamterene components of TRIAMIZIDE are similar. The onset of diuresis with the tablets takes place within one hour, peaks at two to three hours and tapers off during the subsequent seven to nine hours.

Indications

TRIAMIZIDE 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. digitalised patients). It can be used alone or in combination with other antihypertensive drugs.

TRIAMIZIDE is indicated in the treatment of oedema associated with congestive heart failure, hepatic cirrhosis and the nephrotic syndrome; also in corticosteroid and estrogen induced oedema and idiopathic oedema.

Dosage and Administration

The treatment of hypertension and oedema 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 oedema, the usual initial adult dose is one or two tablets, twice daily after meals. Some patients may be maintained on one tablet daily on 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 TRIAMIZIDE should be added at reduced dosage – one half the usual dosage – particularly if it is ganglionic blocking agent.

Adjust dosage as indicated.

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

Contraindications

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

Warnings and Precautions

Patients should not be placed on dietary potassium supplements or potassium salts in conjunction with TRIAMIZIDE therapy, unless they develop hypokalaemia or their dietary intake of potassium is markedly impaired. Because of potassium conserving effect of the triamterene component, hypokalaemia is an uncommon occurrence with the use of these tablets. 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 hydrochlorothiazide/triamterene therapy. Hyperkalaemia 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 hyperkalaemia, TRIAMIZIDE 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 TRIAMIZIDE therapy when using high doses for prolonged periods or in patients on a salt-restricted diet. Periodic serum electrolyte determinations are recommended during therapy.

TRIAMIZIDE 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.

TRIAMIZIDE 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 azoturia increases, discontinue TRIAMIZIDE.

Thiazide may cause hyperglycaemia and glycosuria and alter insulin requirements in diabetes. Hyperuricemia may be observed with possible occurrence of gout. TRIAMIZIDE 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 anaemia have been reported with thiazides. It is recommended that patients treated with TRIAMIZIDE be observed regularly for the possible occurrence of blood dyscrasias.

Triamterene has been reported, in higher doses, to increase the incidence of renal stones.

Use 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 foetus. These hazards include foetal or neonatal thrombocytopenia or pancreatitis (see Adverse Effects).

Use in Lactation:

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

Use in Children:

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

Adverse Effects

Adverse effects observed in association with the use of these tablets include muscle cramps, weakness, dizziness, headache and dry mouth; anaphylaxis, rash, urticaria, photosensitivity and purpura; nausea and vomiting, diarrhoea 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 these tablets, although a casual relationship has not been established.

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

Interactions

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

TRIAMIZIDE 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 TRIAMIZIDE should be undertaken with caution.

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

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

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.

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Prescription Medicine.

Package Quantities

Bottles of 100 and 500 tablets.

Further Information

Triamterene has been found in renal stones in association with other usual calculus components.

Name and Address

Mylan New Zealand Ltd
PO Box 11-183
Ellerslie
AUCKLAND
Telephone: 09-579-2792

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