(1)報核仿單標籤以粘貼全型實物爲原則。

註 (2)仿單標籤等實物過大或印於玻璃金屬容器等不便於粘貼時得附送現品並將照相影本代替粘貼報核。

Dyazide® – Prescribing Information

DESCRIPTION

Each round, peach-coloured, scored, 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 complements 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. The onset of diuresis with 'DYAZIDE' takes place within one hour, peaks at two to three hours and tapers off during the subsequent seven to nine hours.

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 and idiopathic 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.

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 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 restricter 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 increases, discontinue 'DYAZIDE'.

Thiazides 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.

單獨服用 thiazide 曾發生感覺異常、黃膽、胰炎、及視物顯黃之情形。

注意事項：

①如患有心臟衰弱、腎臟病及肝臟病，可能因服用任何類利尿劑，而發生電解質不平衡，本品也偶爾會發生。因 Dyazide 含有

可能會減少氯離子保

症情況，會增加毛地

Noreinephrine 會減

痺作用，因此患者於

事項：

未作生育研究，

azide 而導致胎兒畸

孕婦人，像一般新藥

利益才使用。

本藥須由醫師處方使

孩不宜使用本品）

始一般用量每日二

需而異，如已服用

用 Dyazide 時，可

azide 以代之。

般用量爲每日二次，

後，患者改服用每日

最高服用量不得超過

有降血壓作用，如想

如果 Dyazide 想和已

在服用之降血壓劑至

須調整用量以適合病

過度劑量之報告。如

質的不平衡，其次是

這些可能發生低血壓

制血壓至正常。

如同其他藥物，如過量服用，沒有

吐，須注意電解質變化和體液平衡

包　　裝：