

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dytac 50mg Capsules
Triamterene 50mg Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 50mg triamterene EP.

3. PHARMACEUTICAL FORM

Opaque, maroon-coloured capsules containing as a yellow, granular powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Triamterene is a potassium-conserving diuretic, thought to act by directly inhibiting the exchange of sodium for potassium and hydrogen in the distal renal tubule.

Potassium-conserving diuretic for the control of oedema in cardiac failure, cirrhosis of the liver or the nephrotic syndrome, and in that associated with corticosteroid treatment. When Dytac is used as an adjuvant to potassium-depleting diuretics, such loss may be inhibited and diuresis enhanced.

4.2. Posology and method of administration

Method of Administration

Oral

Dosage

Adults only: When given alone, the usual dosage range is from 3 to a maximum of 5 Dytac capsules a day. The optimal daily dosage is 4 capsules, given in divided doses after breakfast and lunch. After the first week,

treatment should preferably be given on alternate days to ensure satisfactory maintenance diuresis without an increase in blood urea levels. When given with another diuretic, lower dosages of both should be used initially.

Elderly: A lower dosage may be sufficient. The normally occurring reduction in glomerular filtration with age should be borne in mind.

4.3 Contraindications

Hyperkalaemia, progressive renal failure, increasing hepatic dysfunction, Addison's disease, known hypersensitivity to the drug and anuria. Routine concomitant administration of potassium supplements, or other potassium-conserving drugs, including ACE inhibitors.

4.4 Special warnings and precautions for use

Use with caution in patients with diabetes mellitus, hepatic or renal insufficiency; in those predisposed to gout since Dytac has been shown in rare instances to elevate uric acid levels; with hypotensive agents since an additive effect may result; and in diabetic nephropathy, due to increased risk of hyperkalaemia.

It is advisable to monitor blood urea, serum potassium levels and electrolytes periodically. This is important in the elderly, those with renal impairment and those receiving concomitant treatment with NSAIDs.

Combinations of folate antagonists and triamterene are not advisable in pregnancy or in patients with hepatic cirrhosis because of the increased theoretical risk of folate deficiency developing.

4.5 Interactions with other medicinal and other forms of interaction

Use with caution with hypotensive agents. When given with another diuretic, lower dosage of both should be given initially. Triamterene reduces excretion of Lithium and may thus precipitate intoxication.

It is advisable to monitor blood urea and serum potassium levels periodically in patients receiving concomitant treatment with NSAIDs. Renal failure, reversible on stopping treatment, has been reported very rarely which may be due to an interaction between triamterene and some NSAIDs.

It has been suggested that the suppression of urinary prostaglandins by NSAIDs could potentiate the nephrotoxic effects of triamterene.

Occasional reports of reduced renal function when triamterene given with indometacin avoid concomitant use.

Triamterene has the following interaction information:

Drugs likely to increase the risk of severe hyperkalaemia when given with triamterene:

- ACE inhibitors angiotensin-II receptor antagonists.
- tacrolimus
- indometacin
- potassium salts.
- trilostane.
- ciclosporin
- aliskiren
- chlorpropamide
- amiloride
- aldosterone antagonists such as eplerenone and spironolactone

Drugs likely to enhance the hypotensive effect when give with triamterene:

- alprostadil
- ACE inhibitors
- drospirenone (monitor serum potassium during first cycle)
- adrenergic neurone blockers
- alcohol
- aldesleukin
- alpha-blockers , also increased risk of first-dose hypotension with post-synaptic alpha-blockers such as prazosin
- general anaesthetics
- angiotensin-II receptor antagonists
- anxiolytics and hypnotics
- with baclofen
- beta-blockers
- calcium-channel blockers
- clonidine
- hydralazine
- levodopa
- MAOIs
- methyldopa
- minoxidil
- diazoxide
- moxislyte
- moxonidine
- nitrates
- phenothiazines
- sodium nitroprusside
- tizanidine

Effects of diuretics is antagonised by following drugs:

- ketorolac
- indometacin
- oestrogens
- corticosteroids

Hypokalaemia caused by diuretics increases risk of ventricular arrhythmias with following drugs:

- sertindole
- pimozone (avoid concomitant use)
- platinum compounds
- atomoxetine
- amisulpride

Increased risk of postural hypotension when diuretics given with tricyclics.

Increased risk of hyponatraemia when diuretics given with carbamazepine

4.6. Pregnancy and lactation

There is no clinical evidence to suggest any associated hazards to the foetus, However triamterene has been found to cross the placenta in humans. Nevertheless, drugs should be avoided in pregnancy unless essential, especially during the first trimester. Triamterene may appear in the breast milk, and if the drug is essential, the patient should stop breastfeeding.

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Triamterene:

Blood and lymphatic system disorders	Rare or very rare (<1/1000, including case reports)	megaloblastic anaemia, pancytopenia
Metabolism and nutrition disorders	Very common or common (>1/100)	hyperkalaemia (incidence is reduced by Furosemide)
	Uncommon (>1/1,000, <1/100)	hyperuricaemia
Nervous system	Uncommon	Headache

disorders	(>1/1,000, <1/100)	
Vascular disorders	Uncommon (>1/1,000, <1/100)	hypovolaemia
Gastrointestinal disorders	Very common or common (>1/100)	nausea, vomiting, diarrhoea
	Uncommon (>1/1,000, <1/100)	dry mouth
Skin and subcutaneous tissue disorders	Uncommon (>1/1,000, <1/100)	Rashes
	Rare or very rare (<1/1000, including case reports)	photosensitivity reactions, pseudoporphyria
Renal and urinary disorders	Uncommon (>1/1,000, <1/100)	elevation of s-creatinine, transient renal insufficiency
	Rare or very rare (<1/1000, including case reports)	Interstitial nephritis, urinary stones
General disorders and administration site conditions	Rare or very rare (<1/1000, including case reports)	serum sickness

Weakness, minor decreases in blood pressure, and rash have been reported. Anaphylaxis is a remote possibility.

Metabolic acidosis occasionally occurs. Electrolyte imbalance may also indicate excessive dosage or be secondary to the condition under treatment.

Renal failure, reversible on stopping treatment, has been reported very rarely and has been due to acute interstitial nephritis or an interaction between triamterene and some NSAIDs.

Triamterene has been found in renal stones both alone and in association with other usual calculus components. There is no evidence that stone formation is increased in patients taking triamterene-containing drugs.

Jaundice and abnormalities of serum levels of liver enzymes, have also been reported.

Triamterene may cause a blue fluorescence of the urine under certain light conditions.

Triamterene interferes with bioassay of folic acid.

4.9. Overdose

Symptoms of electrolyte imbalance, especially hyperkalaemia, are likely. Symptoms include nausea, vomiting, weakness, lassitude, muscular weakness, hypotension and cardiac arrhythmias. Treatment consists of gastric lavage with careful monitoring of electrolytes and fluid balance. Cardiac rhythm should be monitored and appropriate measures taken to correct hyperkalaemia as necessary. There is no specific antidote. Renal dialysis may be of some benefit in cases of severe overdosage.

Triamterene is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It has been estimated to have a plasma half-life of about 2 hours. Triamterene is extensively metabolised and is mainly excreted in the urine in the form of metabolites with some unchanged triamterene; variable amounts are also excreted in the bile.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Triamterene is a potassium-conserving diuretic thought to act by directly inhibiting the exchange of sodium for potassium and hydrogen in the distal renal tubule.

5.2. Pharmacokinetic properties

Onset of action is 2-4 hours after ingestion. Diuresis generally tapers off 7-9 hours after administration. Triamterene is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It has been estimated to have a plasma half life of about 2 hours. Triamterene is extensively metabolised and is mainly excreted in the urine in the form of metabolites with some unchanged triamterene; variable amounts are also excreted in the bile.

5.3. Preclinical safety data

No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium stearate
Lactose
Black Iron oxide E172
Erythrosine E127
Titanium Dioxide E171
Gelatin

6.2. Incompatibilities

None known

6.3. Shelf life

36 months for blister packs

60 months for securitainers/amber glass bottles/polyethylene vials.

6.4. Special precautions for storage

Store in a dry place.

6.5. Nature and contents of container

Polypropylene securitainers/amber glass bottles/polyethylene vials contain 30 or 250 capsules Blister packs contain 30 capsules.

6.6. Instructions for use/handling

None.

7 MARKETING AUTHORISATION HOLDER

Goldshield Group Limited
NLA Tower
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CR0 0XT
Trading as: Goldshield Pharmaceuticals

8. MARKETING AUTHORISATION NUMBER(S)

PL 10972/0017

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

January 1994

10 DATE OF REVISION OF THE TEXT

28/09/2010