SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Triamterene/Chlortalidone 50mg/50mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlortalidone BP 50mg

Triamterene BP 50mg

3 PHARMACEUTICAL FORM

Coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

i) Management of mild to moderate hypertension.

ii) Oedema associated with congestive cardiac failure, nephrosis, corticosteroid or oestrogen therapy.

iii) Ascites associated with hepatic cirrhosis.

4.2 Posology and method of administration

Hypertension

Usually one tablet daily taken after breakfast. If necessary the dose may be increased to two tablets taken once daily.

Oedema

The usual dose is one tablet daily taken after breakfast. If oedema persists after seven to ten days the dose may be increased to two tablets daily.

Dosage in children has not been established and this medicine is recommended for the treatment of adults only.

The elderly may require a lower dosage schedule.

4.3 Contraindications

Hypersensitivity to the individual components or to other sulphonamide-derived drugs. Progressive renal failure. Concomitant lithium therapy.
Triamterene/Chlortalidone tablets should not be used in the presence of hyperkalaemia (plasma potassium above 5.0 mmol/litre) or in patients receiving other potassium-sparing agents such as spironolactone or amiloride.

4.4 Special warnings and precautions for use

Caution should be exercised in patients with severe kidney disease, impaired liver function or progressive liver disease.

As with thiazide diuretics and chlortalidone, treatment with Triamterene/Chlortalidone tablets may result in hyperuricaemia or the precipitation of acute gout in certain patients.

Potassium supplements should not be given with this medicine except in the presence of hypokalaemia.

Chlortalidone has, in common with other sulphonamide diuretics, occasionally aggravated or precipitated diabetes mellitus. The effect is usually reversible on cessation of therapy.

Chlortalidone and related drugs may decrease serum protein bound iodine levels without signs of thyroid disturbance.

Triamterene may cause a decreasing alkali reserve, with the possibility of metabolic acidosis.

Although no clinically significant hyperkalaemia has occurred in studies with Triamterene/Chlortalidone tablets, all potassium conserving diuretic combinations can cause an abnormal elevation of plasma potassium. It is recommended that measurements of potassium are made at the time of dosage adjustments and at appropriate intervals during therapy, particularly in elderly or diabetic patients with confirmed or suspected renal insufficiency.

Signs or symptoms of hyperkalaemia include paresthesia, muscular weakness, fatigue, flaccid paralysis of the extremities, bradycardia, shock and ECG abnormalities. If hyperkalaemia occurs in patients taking this medicine, it should be withdrawn, a diuretic substituted and potassium intake restricted. If the plasma potassium level exceeds 6.5 mmol per litre, active measures should be taken to reduce it. Such measures include the intravenous administration of sodium bicarbonate solution or oral or parenteral glucose with a rapid-acting insulin preparation.

If progressive renal impairment becomes evident, Triamterene/Chlortalidone therapy should be withdrawn and alternative therapy instituted if necessary.

Choroidal effusion, acute myopia and secondary angle-closure glaucoma: Sulfonamide or sulfonamide derivative drugs can cause an idiosyncratic reaction resulting in choroidal effusion with visual field defect, transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue drug intake as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Triamterene/Chlortalidone tablets may add to or potentiate the action of other antihypertensive drugs. Any tendency to orthostatic hypotension during treatment with Triamterene/Chlortalidone tablets may be aggravated by concomitant alcohol, barbiturates or narcotics. Chlortalidone and related drugs may increase the responsiveness to tubocurarine.

4.6 Pregnancy and lactation

Thiazide diuretics have been shown to cross the placenta and also to appear in breast milk. In rare instances, thrombocytopenia, pancreatitis or hypokalaemia have been reported in newborn infants of mothers treated with thiazide diuretics. The use of this medicine in pregnant or nursing mothers should therefore be avoided unless essential.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects are similar to those that have been associated with thiazide therapy and include nausea, dry mouth, constipation, leg cramp, headaches, dizziness and fatigue.

Eye disorders: choroidal effusion (frequency not known).
Cases of choroidal effusion with visual field defect have been reported after the use of thiazide and thiazide-like diuretics.

Rare cases of megaloblastic anaemia have been reported in association with triamterene.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The stomach contents should be emptied immediately. Treatment should be symptomatic and supportive with correction of electrolyte imbalance and fluid depletion. No specific antidote exists for Triamterene/Chlortalidone tablets.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This medicine contains a long acting potassium sparing diuretic and antihypertensive, and is of particular value in conditions where potassium conservation is important.

Chlortalidone blocks the reabsorption of sodium and chloride in the cortical diluting segment of the nephron thereby increasing both the quantity of sodium delivered to the distal tubule and the volume of water excreted. However, a portion of the additional sodium reaching the distal tubule is exchanged at this site for potassium and hydrogen. Triamterene is a weak diuretic found to spare potassium. It acts on the membrane of the lumen in the collecting duct of the kidney to inhibit the reabsorption of sodium and decrease the passive forces influencing the secretion of potassium and hydrogen.

5.2 Pharmacokinetic properties

Triamterene is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It is extensively metabolised and mainly excreted in the urine as metabolites with some unchanged triamterene.

Chlortalidone is also incompletely absorbed from the gastro-intestinal tract and is mainly excreted unchanged in the urine.

From a bioequivalence single dose study:

Serum triamterene levels:

C max (ng/ml) mean: 67.05

T max (h) median: 1

AUC to 24 hours mean: 257.75

Urinary chlortalidone levels:

Peak urinary excretion rate (mg/h) mean: 0.804

Time to peak urinary excretion rate (h) median: 3

Total amount excreted by 120 hours (mg) mean: 15.856

AUC to 120 hours mean: 15.85

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP

Starch BP

STA RX 1500 starch

Microcrystalline cellulose BP

Sodium starch glycollate BP

Magnesium stearate BP

Hypromellose

Polyethylene glycol 4000

Polyethylene glycol 400

Antifoam

Sodium propyl hydroxybenzoate BP

Carnauba wax BP

Titanium dioxide E171

Sunset Yellow E110

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a dry place, below 25°C.

6.5 Nature and contents of container

PVC/aluminium blister strips containing 7 tablets.

28 tablets (4 strips) are packed into cardboard cartons.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

DHP Healthcare Limited

26 Pickering Street

Maidstone

Kent ME15 9RS

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00111/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 June 2004.

10 DATE OF REVISION OF THE TEXT

13/07/2020