PROFESSIONAL INFORMATION FOR

ULTIPOT

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ULTIPOT (600 mg slow release film coated tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each slow release film coated tablet contains 600 mg potassium chloride equivalent to 315 mg potassium (8 mmol).

Sugar free.

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Slow release film coated tablet.

Pale yellow, oblong, biconvex film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ULTIPOT is indicated for the prophylaxis and treatment of hypokalaemia.

4.2 Posology and method of administration

Posology

The dosage should be adapted to the cause and the degree of the manifest hypokalaemic state. Depending on the patient's individual requirement, a daily dosage of 6 to 12 tablets, in several divided doses, should be given. Not more than 2 tablets (16 mmol) should be given in a single dose.

Paediatric population

Safety and efficacy in children has not been established.

Method of administration

The tablets must be swallowed whole and should not be chewed or broken before swallowing.

4.3 Contraindications

ULTIPOT is contraindicated in:

- Patients with known hypersensitivity to potassium chloride or to any of the excipients used in the formulation of ULTIPOT (see **section 6.1**).
- Patients with hyperkalaemia, untreated Addison's disease, hyporeninaemia, hypoaldosteronism, metabolic acidosis, heat cramps and acute dehydration.
- Patients with severe liver diseases and gastrointestinal ulceration or obstruction.
- Patients with renal insufficiency: due to the possibility of hyperkalaemia being precipitated, potassium salts should not be administered to those patients being treated with potassium-sparing diuretics (aldosterone antagonists, triamterine or amiloride).
- Concomitant use of other potassium supplements or intravenous potassium.

4.4 Special warnings and precautions for use

Hyperkalaemia: those patients who have impaired potassium excretion, should not be given ULTIPOT, since this could precipitate hyperkalaemia and cardiac arrest.
Potentially fatal hyperkalaemia can develop rapidly and may be asymptomatic. Patients with diseases or conditions which impair the excretion of potassium, should be monitored very carefully when administering potassium salts, serum potassium concentration should be checked and the necessary dosage adjustments made.

Gastrointestinal lesions: if a patient develops symptoms of pronounced nausea, severe vomiting, severe abdominal pains, flatulence, diarrhoea or gastrointestinal bleeding, while using ULTIPOT, the preparation should be withdrawn immediately. The above signs and symptoms may be indicative of ulceration or perforation in the gastrointestinal tract. Those at risk are patients with oesophageal stasis, peptic or gastric ulcerations, delayed intestinal transit or intestinal ischaemia due to atherosclerotic vascular disease.

ACE-inhibitors: ACE-inhibitors may cause retention of potassium due to inhibition of aldosterone production, thus, those patients using ACE-inhibitors should be monitored closely upon administration of potassium supplementation (see **section 4.5**).

Use in elderly patients: Caution should be observed in the elderly or in patients where renal or adrenocortical insufficiency or heart disease is present or a possibility, as the risk of developing of hyperkalaemia is increased. Monitoring of serum electrolytes is indicated in these instances, as well as during protracted substitution of potassium.

Use in renal insufficiency: Care should be exercised in patients with cardiac disease, or extensive tissue destruction as occurs with severe burns.

Use in patients suffering from stomas: The administration of ULTIPOT is not advised in those patients suffering from stomas, due to an altered intestinal transit time. ULTIPOT should be given with caution to patients receiving medication that may cause hypomagnesaemia. Plasma magnesium levels should be assessed and any necessary corrections made in these patients.

Paediatric population

Safety and efficacy in children has not been established.

4.5 Interaction with other medicines and other forms of interaction

Potassium supplements should be used with caution, in patients receiving medicines that increase serum-potassium-concentrations. These include potassium-sparing diuretics, ACE inhibitors, and cyclosporin and medicines containing potassium salts, such as penicillin, digoxin, lithium, NSAID's, heparin and beta-blockers. Antimuscarinics delay gastric emptying and consequently may increase the risk of gastrointestinal adverse effects in patients receiving solid oral dosage forms of potassium.

4.6 Fertility, pregnancy and lactation

The safety of ULTIPOT in pregnancy and breastfeeding has not been established.

4.7 Effects on ability to drive and use machines

The adverse effects of ULTIPOT such as confusion, hypotension, cardiac arrhythmias, heart block, cardiac arrest and nausea (see **section 4.8**) may affect the patient’s ability to drive or operate machinery. Therefore, the patient must first see how ULTIPOT affects them before performing these tasks.

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories: frequent, less frequent and frequency unknown.

MedDRA system organ Class	Frequency	Side effects
Nervous system disorders	*Frequency unknown:*	Confusion.
Cardiac disorders	*Less frequent:*	Hypotension, cardiac arrhythmias, heart block and cardiac arrest.
Gastrointestinal disorders	*Frequent:*	Nausea, vomiting, diarrhoea, stomach pain, discomfort or gas (mild).
	Less frequent:	Abdominal or stomach pain, cramping or soreness, gastrointestinal ulceration, chest or throat pain, especially when swallowing, blood in the urine, blood in vomit, coughing up blood, black stools.
Skin and subcutaneous tissue disorders	*Less frequent:*	Pruritus, skin rash and urticaria.
Musculoskeletal and connective tissue disorders	*Frequency unknown:*	Paraesthesia of the extremities, muscle weakness, and paralysis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Acute over dosage of ULTIPOT tablets may cause nausea, vomiting, diarrhoea and abdominal cramps.

Untoward effects are mainly cardiovascular, such as hypotension, shock, ventricular dysrhythmias, bundle branch block, ventricular fibrillation; and neuromuscular, such as paraesthesia, convulsions, areflexia, flaccid paralysis of striated muscle which may precipitate respiratory paralysis. Elevation of serum potassium concentrations and typical ECG changes are also observed (increased amplitude and peaking of T-wave, disappearance of P-wave, widening of QRS complex, and ST depression).

Gastrointestinal ulceration. Cardiac toxicity may be treated with intravenous administration of calcium salts with ECG monitoring.

Further treatment is symptomatic and supportive.

Hyperkalaemia following chronic over dosage or as a result of drug interactions: Potassium containing foods, medications and potassium-sparing diuretics must be withdrawn. Serum potassium may be reduced by infusions with glucose and insulin. When treating hyperkalaemia, lowering of the serum potassium concentrations too rapidly can produce digitalis toxicity in patients who have been previously stabilised on digitalis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.24 Mineral substitutes, electrolytes

ATC code: A12BA01

Potassium is an electrolyte in the human body which is involved in intracellular and extracellular physiological processes.

5.2 Pharmacokinetic properties

Absorption

Potassium salts other than the phosphate, sulfate, and tartrate are generally readily absorbed from the gastrointestinal tract.

Elimination

Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange for sodium or hydrogen ions. Some potassium is excreted in the faeces and small amounts may also be excreted in sweat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet cores:

Colloidal silicon dioxide,

macrogol 6000,

magnesium stearate and

stearic acid.

Coating ingredients:

Candurin silver lustre,

dibutyl phthalate,

Eudragrit RL-100,

Eudragrit RS-100,

iron oxide black,

iron oxide yellow,

povidone K-25,

talc purified and

titanium dioxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C, protected from light and moisture.

6.5 Nature and contents of container

ULITPOT tablets are available in containers of 30, 100 and 500. The tablets are packed in white plastic containers with white plastic closures.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 2

Junxion Park

10 Elephant Lane

Century City

7441

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

35/24/0370

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 19 April 2013

Latest renewal: Not applicable.

10. DATE OF REVISION OF THE TEXT

16 September 2024