SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Potassium chloride 600 mg tablets
Potrelease TR

2. Qualitative and quantitative composition
Each tablet contains 600 mg of potassium chloride.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Tablet.

Yellow, round-shaped film-coated tablet with deep concave surfaces.

4. Clinical particulars

4.1 Therapeutic indications
a. Hypokalemia (treatment) - Potassium chloride is indicated in patients with hypokalemia with or without metabolic alkalosis, in chronic digitalis intoxication and patients with hypokalemic familial periodic paralysis.
b. Hypokalemia (prophylaxis) - Potassium chloride is indicated to prevent hypokalemia in patients whose dietary intake of potassium is inadequate and who are taking digitalis and diuretics.
c. Potassium chloride is also indicated in patients who suffer from hepatic cirrhosis with ascites, aldosterone excess with normal renal function, severe diarrhoea and potassium-losing nephropathy.

4.2 Posology and method of administration
Oral administration.

Adults
600 mg to 1200 mg of potassium chloride (or equivalent of 8 mEq to 16 mEq of potassium) three times a day.

Paediatrics
Use is not recommended.

4.3 Contraindications
a. Severe renal impairment with oliguria or azotemia.
b. Untreated Addison's disease.
c. Adynamia episodica – hereditarian.
d. Acute dehydration.
e. Heat cramps.
f. Hyperkaleamia.
g. Gastrointestinal obstruction, abnormal motility or ulceration.
h. Metabolic acidosis.

4.4 Special warnings and precautions for use

Gastrointestinal disorders
Potassium chloride, alone or in combination with other medications may induce ulceration in the gastrointestinal tract, in particular the lower oesophagus and small bowel. This possibility is increased in patients with local, functional or mechanical disorders of the gastrointestinal tract, with cardiovascular disease, or in those on prolonged therapy or receiving anticholinergics. Symptoms or signs suggesting ulceration or obstruction of the tract should be regarded as reasons to discontinue medication immediately (see section 4.8). Patients with ostomies may have altered intestinal transit times and are better treated with other forms of potassium salts. The insoluble tablet matrix may be present in the faeces. Patients should be advised that this is normal.

Hyperkalaemia
Potassium salts should only be administered with extreme caution to patients with renal dysfunction, hepatic disease (because of the risk of hyperkalaemia), history of or existent peptic ulceration. Monitoring of serum potassium and othe relectrolytes is particularly necessary in patients with diseases of the heart and kidneys. Slow K should be used with caution in patients receiving any drug known to have a potential for hyperkalaemia, such as ACE inhibitors, angiotenin–II-receptor antagonists, NSAIDs (e.g., indomethacin), beta-blockers, heparin, digoxin and ciclosporin (see also section 4.5 Interaction with other medicinal products and other forms of interaction). Treatment Monitoring Periodic serum potassium determinations are recommended during long term supplementation, especially in clinical conditions which carry a risk of hyperkalaemia (e.g., impaired renal function or heart disease) (see also section 4.5 Interaction with other medicinal products and other forms of interaction). Other In some patients, diuretic induced magnesium deficiency will prevent restoration of intracellular deficits of potassium so that hypomagnesaemia should be corrected at the same time as hypokalaemia.

4.5 Interaction with other medicinal products and other forms of interaction
The following drug interactions and/ or related problems have been selected on the basis, of their potential clinical significance (possible mechanism in parentheses where appropriate - not necessarily inclusive).

Note: Combinations containing any of the following medications, depending on the amount present may also interact with this medication.

Arenocorticoids, glucocorticoids, especially with significant mineralocorticoid activity, or Corticotrophin (ACTH)
Concurrent use of these medications may decrease the effects of potassium supplements on serum potassium concentrations, close monitoring of serum potassium concentration is recommended.

Antimuscarinics, especially atropine and related compounds
Concurrent use of potassium chloride supplements, especially those with wax matrix, may increase the severity of gastrointestinal lesions produced by potassium chloride alone. Patients should be carefully monitored endoscopically for evidence of lesions.

Blood from the blood bank (may contain up to 30 mEq of potassium per litre of plasma or up to

65 mEq per litre of whole blood when stored for more than 10 days) or **diuretics, potassium-sparing, such as amiloride, spironolactone, or triamterene** or **low-salt milk** (may contain up to 60 mEq of potassium per litre) or **potassium-containing medications** or **salt substitutes** (most contain a substantial amount of potassium)
Concurrent administration with potassium supplements tends to promote serum potassium accumulation with possible resultant hyperkalaemia, especially in patients with renal insufficiency.

Calcium salts
Parenteral administration antagonizes the cardiotoxicity of hyperkalaemia, calcium should be used cautiously in patients receiving potassium and digitalis medications because of the danger of precipitating cardiac arrhythmias.

Captopril
Concurrent administration may result in hyperkalaemia since the reduction of aldosterone production induced by captopril may lead to an elevation of serum potassium.

Digitalis glycosides
Potassium supplements are not recommended for concurrent use in digitalized patients with severe or complete heart block. However, if potassium supplements need to be used to prevent or correct hypokalaemia in digitalized patients, carefully monitoring serum potassium concentrations is extremely important to avoid hyperkalaemia, which is very dangerous in digitalized patients.
Exchange resins, sodium cycle, such as sodium polystyrene sulfonate
Whether administered orally or rectally, serum potassium concentrations are reduced by sodium replacement of the potassium; fluid retention may occur in some patients because of the increased sodium intake.

Glucose-insulin infusion or **sodium bicarbonate infusion**
Serum potassium concentrations are reduced by promoting a shift of potassium ions into the cells.

Laxatives
Chronic use or overuse of laxatives may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract.

Quinidine
Concurrent use with potassium supplements usually enhances quinidine's antiarrhythmic effects.

Vitamin B12
Extended-release dosage forms of potassium may reduce the absorption of vitamin B12 from the gastrointestinal tract, thus increasing the requirement for vitamin B12.

4.6 Pregnancy and lactation

Pregnancy
For potassium chloride no clinical data on exposed pregnancies are available. There is no indication in animal studies of direct or indirect harmful effects concerning pregnancy, embryonal/foetal development, parturition or postnatal development (see also section 5.3 Preclinical safety data).

Lactation
The excretion of potassium in milk has not been studied in animals or humans. As a rule, no drugs should be taken during the first three months of pregnancy and the risks and benefits of taking drugs should be carefully considered throughout pregnancy. Because of gastrointestinal hypomotility associated with pregnancy, solid forms of oral potassium preparations should be given to pregnant women only if considered essential. The normal K+ content of human milk is about 13 mmol/litre. Since oral potassium becomes part of the body's potassium pool, provided this is not excessive, potassium chloride can be expected to have little or no effect on the potassium level in human milk. Potassium chloride should only be given during breastfeeding when the expected benefit to the mother outweighs the potential risk to the baby.

Fertility
There are no special recommendations.

4.7 Effects on the ability to drive and use machines
No effects on the ability to drive and use machines have been observed.

4.8 Undesirable effects

Those indicating the need for medical attention
Confusion, irregular heartbeat, numbness or tingling in hands/feet/lips, shortness of breath or difficulty in breathing, unexplained anxiety, unusual tiredness or weakness and weakness or heaviness of legs.

Note: These side effects are considered rare when oral dosage forms of potassium are administered to patients having normal renal function. Irregular heartbeat is usually the earliest clinical indication of hyperkalaemia and is readily detected by electrocardiogram.

Those indicating need for medical attention only if they continue or are bothersome
Diarrhoea, nausea, stomach pain and vomiting.

Note: These side effects occur more frequently when the medication is not taken with food.

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 e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose
Treatment of hyperkalaemia includes discontinuing foods and medication which contain potassium and any potassium-sparing diuretics; intravenous administration of insulin in 10 to 25% dextrose injection (using IO units of insulin per 20 grams of dextrose) at a rate of 300 to 500 ml of solution per hour, correction of any existing acidosis with intravenous sodium bicarbonate and utilisation of exchange resins, hemodialysis or peritoneal dialysis. Caution must be observed when treating hyperkalaemia in digitalized patients since the rapid reduction of serum potassium concentrations

may induce digitalis toxicity.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological classification: 23.1.2 Oral electrolyte replacement.

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5.2 Pharmacokinetic properties

Onset and duration
Peak elevation of serum potassium levels following SR preparations is highly delayed (2 hours) compared to liquid form (I hour). Effect on serum potassium is generally confined to the first 3 hours after dosing.

Plasma levels
(May vary depending on laboratory) 3.5 - 5 mEq/L (adult and child); 5 - 7.5 mEq/L (newborn) and total body stores are approximately 50 mEq/kg or 3500 mEq. As a general rule, a decrease of I mEq/L in serum potassium reflects an IO - 20 % total body deficit. However, there is considerable variation, signs of hypokalaemia appear below 2.5 mEq/L and levels above 7 mEq/L are dangerous. Clinical signs of hyperkalaemia are not reliable indicators of serum levels. Alkalosis decreases levels and acidosis increases levels.

Fate
When initially administered, the rates of absorption and excretion are more rapid with the liquid than the SR forms. However, bioavailability is the same when administered long-term (78-90%). Approximately 10 mEq/day are eliminated in faeces, 7.5 mEq/ Lin sweat and 60 - 90 mEq/day in urine.

5.3 Preclinical safety data

Preclinical data do not support a special hazard for humans based on conventional studies of acute toxicity, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

The acute and repeated-dose oral toxicity of potassium chloride in animals is low. Gastrointestinal irritant effects have been observed in rhesus monkeys at high oral dosages of potassium chloride. Some positive results in *in vitro* genotoxicity assays were attributed to very high concentrations of potassium chloride. Carcinogenicity studies in rats administered potassium chloride in-feed were negative. Limited information from oral developmental studies in rodents indicates there is no ill effect on offspring. There is no evidence from animal experiments that oral potassium chloride exerts any teratogenic effects or reproductive toxicity which would be relevant to man.

6. Pharmaceutical particulars

6.1 List of excipients

Tablet core
Maize starch
Gelatin
Quinoline yellow 70%
Beeswax
Cetostearyl alcohol
Magnesium stearate
Purified water

Tablet coat
Ethyl cellulose
Tween 80
Acetone
Isopropyl alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of the container

The tablets are packed in an HDPE bottle, closed with a polypropylene cap.

Pack size: 100's.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

Cospharm Investments (Pvt) Limited
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8. MANUFACTURER

SM Pharmaceuticals
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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/23.1.2/6443
Zimbabwe category for distribution: Pharmacist Initiated Medicines (P.I.M.)

10. DATE OF REVISION OF TEXT

September 2023