SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

POTCL

Potassium Chloride for Injection Concentrate USP

Strength:

150 mg/ml – 10 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Sr. No.	Particulars	Grade	Qty./ml	Function
1.	Potassium Chloride	USP	150 mg	Active

For list of full of excipients see section 6.1.

3. PHARMACEUTICAL FORM:

Solution for Injection

A clear colourless solution.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

The treatment of potassium depletion in patients with hypokalemia; treatment of digitalis intoxication. The I.V. route is indicated when the patient is unable to take potassium orally or if hypokalemia is severe.

4.2 Posology and method of administration:

Route of administration: For I.V. Infusion.

For I.V. administration only; dilute before infusing. The dose and rate of injection are dependent upon the individual patient's condition. In patients whose serum Potassium Concentration is above 2.5 mEq/L, the rate of infusion should not exceed 10 mEq/hour, in a concentration less than 30 mEq/L. The total dose should not exceed 200 mEq/24 hours.

If urgent treatment is required (serum Potassium Concentration less than 2 mEq/L with ECG changes or paralysis), infuse Potassium in a suitable concentration at a rate of 40 mEq/

hour, up to a maximum of 400 mEq/24-hour period. In critical states, Potassium may be infused in saline (unless saline is contraindicated) rather than in dextrose solutions, as the latter may decrease serum Potassium Concentrations.

4.3 Contraindications:

Renal impairment with oliguria or azotemia, untreated Addition's disease, hyperadrenalism associated with adrenogenital syndrome, extensive tissue breakdown as in severe bums, acute dehydration, heat cramps, adynamia episodica hereditaria and hyperkalemia of any etiology.

4.4 Special warnings and precautions for use:

Manufacturers' warnings in clinical states:

In patients with impaired mechanisms for excreting potassium, administration of potassium salts can produce hyperkalemia and cardiac arrest. This is of particular concern in patients given I.V. potassium. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic.

Precautions:
The use of potassium salts in patients with chronic renal disease, adrenal insufficiency or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g. spironolactone and triamterene), since the simultaneous administration of these agents can produce severe hyperkalemia.

In patients on a low salt diet, hypokalemic hypochloremic alkalosis is a possibility that may require chloride as well as potassium supplementation.

The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the ECG and the patient's clinical studies.

Potassium should be used with caution in diseases associated with heart block since increased serum potassium may increase the degree of block.

Parenteral potassium chloride solutions may cause pain if given in a small vein.

4.5 Interaction with other medicinal products and other forms of interaction:

Increased risk of severe hyperkalaemia with the following
• ACE-inhibitors
• Aliskerin
• Angiotensin-II receptor anatagonists
• Potassium sparing diuretics such as: amiloride, spironolactone and triamterene and aldosterone antagonists
• Ciclosporin
• Tacrolimus (not topical formulations)
Particularly close monitoring required with these and any other medicines or conditions that may increase potassium levels.
Further reductions in potassium occurs with glucose infusions.

4.6 Fertility, pregnancy and lactation:

Potassium chloride should be used during pregnancy or lactation only under the supervision of the prescribing physicianif considered essential by the physician.

4.7 Effects on ability to drive and use machines:
Nil.

4.8 Undesirable effects:

The symptoms and signs of potassium intoxication include paresthesia of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, fall in blood pressure, cardiac arrhythmias and heart block. Hyperkalemia may exhibit the following ECG abnormalities: disappearance of the P-wave, widening and

slurring of QRS complex, changes of the S-T segment, tall peaked T-waves. Nausea, vomiting, diarrhea and abdominal discomfort have been reported.

4.9 Overdose:

Symptoms: If excretory mechanisms are impaired or if I.V. Potassium is administered too rapidly, potentially fatal hyperkalemia can result. However, hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic ECG changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. Should any of these manifestations occur, discontinue administration immediately.

Treatment: If hyperkalemia develops, the following measures should be considered:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. I.V. administration of 300 to 500 mL/hour of 10% dextrose solution containing 10 to 20 units of insulin/1000 mL
3. Correction of acidosis, if present, with I.V. Sodium Bicarbonate.
4. Use of exchange resins, hemodialysis, or peritoneal dialysis.
5. Calcium gluconate.

In treating hyperkalemia in digitalized patients, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

MUST BE DILUTED PRIOR TO INJECTION

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group: Electrolyte solutions; ATC Code: B05XA01

Active ion transport by the sodium-potassium ATP ASE carrier maintains a high gradient of potassium across the plasma membrane. Intracellular concentrations of potassium are about 150 mEq per litre while the plasma concentration is in the range of 3.5 to 5 mEq per litre, although there is a modest variation from one cell type to another.

Potassium plays a vital physiological role in maintenance of normal electrical excitability of nerve and muscle. It is also important in the genesis and correction of imbalances of acid-base metabolism.

In acute hypokalaemia, parenteral administration of potassium chloride promptly corrects the deficit in plasma potassium concentration and restores normal physiological function to potassium-dependent systems.

5.2 Pharmacokinetic properties:

Absorption

Potassium is an essential dietary constituent and is readily absorbed from the gastro-intestinal tract. Accumulation of potassium by cells occurs via an energy-dependent mechanism that extrudes sodium. Active ion transport systems maintain a high gradient of potassium across the plasma membrane, resulting in plasma concentrations of about 3.5 to 5mEq per litre and intracellular concentrations of approximately 150 mEq per litre.

Distribution

As a consequence of the large volume of distribution and the rapid response of the kidney, intracellular and extracellular concentrations of potassium are normally maintained within relatively narrow limits. However, when potassium is administered

as a drug, the factors that govern the rate and extent of its distribution are of critical importance. Although administration of potassium will not significantly increase the total body content of the ion, it may easily raise the extracellular concentration excessively. Because it is the extracellular concentration of potassium that determines life-threatening toxicity, awareness of the transient concentration achieved in plasma should govern the use of potassium therapy.

Elimination

Potassium is excreted mainly by the kidneys. It is freely filtered at the glomerulus and is mainly absorbed in the proximal tubules, so that by the time the tubular fluid reaches the late distal tubules, it contains less than 10% of the amount of potassium in the original glomerular filtrate. Normally, considerable amounts of potassium are secreted into the distal tubules and secretory transport is extremely important for the control of plasma potassium concentration.

5.3 Pre-clinical Safety Data:

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients:

Water for Injection BP

6.2 Incompatibilities:

Incompatibilities have been reported with dobutamine hydrochloride, amphotericin, amikacin sulphate and fixed oil emulsions.

6.3 Shelf – life:

24 Months

6.4 Special precautions for storage:

Store below 30°C., protected from light. Do not freeze.

6.5 Nature and contents of container:

5 ampoules of 10 ml flint ampoule packed in inner pack, further packed in a parcel pack.

6.6 Special Precautions for Handling and Disposal:

Warning: Must be diluted before use.
Dilute before use with not less than 50 times its volume of Sodium Chloride Injection or another suitable diluent. Discard if cloudy or deposit present.
Use as directed by the physician.
If only part used, discard the remaining solution.
Keep out of reach of children.

7. MARKETING AUTHORIZATION HOLDER:

M/s. NEON LABORATORIES LIMITED
140, Damji Shamji Industrial Complex,
28, Mahal Indl. Estate, Mahakali Caves Road,
Andheri (East), Mumbai - 400 093

8. MARKETING AUTHORIZATION NUMBER:

NEO/IND/42

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORISATION:

Date of first authorization: 04-11-2019

10. DATE OF REVISION OF THE TEXT:

JULY 2023

11. REFERENCE

- Potassium Chloride Concentrate BP, 15% w/v, 1.5g in 10ml - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

- Potassium Chloride Concentrate BP, 15% w/v, 1.5g in 10 ml - https://dailymed.nlm.nih.gov/dailymed/