VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Kaliumklorid (potassium chloride) EQL Pharma 750mg prolonged-release tablets are intended to be used to prevent or treat low levels of potassium in the blood. Potassium is a mineral that is found in many foods and is needed for several functions of the body. Normal blood levels of potassium are critical for maintaining normal heart rhythm. Both low and high levels can lead to abnormal heart rhythm. Potassium levels in the blood are easily measured by routine blood tests.

Low potassium levels (hypokalaemia)
The most common reason causing potassium levels to fall is due to diuretic medications, the loss from the gastrointestinal tract, eg. vomiting, diarrhoea, or from kidney failure.
Symptoms of low potassium levels are usually mild. Common symptoms are weakness, tiredness, cramping in arms and/or legs, nausea, vomiting, palpitations (feeling of the heart beating fast).
Hypokalaemia is treated with potassium chloride replacement and will be directed by the type and severity of the person´s symptoms.
Hypokalaemia is frequently encountered in clinical medicine and has been estimated to occur in approximately 20% of patients admitted to general internal medicine service. (Hypokalemia, or Low Potassium, By Shawna Kopchu R.N.,13 jul 2008).

VI.2.2 Summary of treatment benefits

Potassium is a mineral that´s crucial for life. Potassium is necessary for the heart, kidneys, and other organs to work normally. Low potassium is possible associated with a risk of high blood pressure, heart disease, stroke, arthritis, cancer, digestive disorders, and infertility. For people with low potassium, doctors sometimes recommend improved diets – or potassium supplements – to prevent or treat some of these conditions.

VI.2.3 Unknowns relating to treatment benefits

None currently.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Hyperkalaemia a) in patients with renal insufficiency, untreated Addison´s disease or severe electrolyte imbalance. b) in patients co-administered with ACE inhibitors, angiotensin-II-receptor antagonists, ciclosporin, NSAIDs, β-blockers, heparin, digoxin, potassium sparing diuretics.	a) For patients with renal impairment dose reduction is required. There is a risk for hyperkalaemia in patients suffering from untreated Addison´s disease or with severe electrolyte imbalance (ie. severe changes in body water content or salts). b) Concomitant treatment with ACE inhibitors or potassium sparing diuretics increases the risk of hyperkalaemia.	Potassium chloride should be administered with caution in patients with heart disease or conditions that can lead to hyperkalemia such as renal or adrenal insufficiency, acute dehydration or extensive tissue damage that occurs in severe burns. Patients suffering from untreated Addison's disease or from severe electrolyte imbalance should not take potassium chloride. Caution is required with concomitant use of potassium sparing diuretics or ACE inhibitors. Treatment should be followed with frequent determination of serum potassium.
Hypersensitivity	Cases of hypersensitive side effects to the active substance or to any of the excipients (Silica Colloidal Anhydrous, Ethylcellulose, Stearyl Alcohol, Surelease Clear, Hypromellose, Talc) are known.	Potassium chloride should not be administered in patients who are hypersensitive to the active substance or to any of the excipients Silica Colloidal Anhydrous, Ethylcellulose, Stearyl Alcohol, Surelease Clear, Hypromellose, Talc.
Gastrointestinal ulcers	Endoscopic investigation following periods of potassium supplementation has shown that potassium supplementation may cause local irritation in the gastrointestinal tract leading to erosion and ulcerations.	Potassium chloride should be administered with caution in patients with acute dehydration and to patients where passage through the gastrointestinal tract may be delayed. Treatment should be stopped if there is severe nausea, vomiting or abdominal pain in the patient.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Intentional or unintentional overdose of potassium chloride	A number of case reports of accidental or deliberate poisoning with potassium have shown that large doses of potassium result in hyperkalaemia and hypernatremia and lead to in changes in acid-base balance and respiratory and heart rates. However, the dose associated with the onset of hyperkalaemia and adverse effects vary depending on potassium status and clearance time.
Increased gastrointestinal adverse effects under co-administration with anticholinergics/antimuscarinics	Caution is required with concomitant use of potassium sparing diuretics or ACE inhibitors due to increased risk of hyperkalaemia. Anticholinergic drugs may reduce gastrointestinal motility. Treatment should be followed with frequent determination of serum potassium.

Missing information

Risk	What is known
Use of potassium chloride in children	The safety and efficacy of potassium chloride in children have not been established. No data are available.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.
The Summary of Product Characteristics and the Package leaflet for Potassium chloride can be found the National Authorities´ web page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable. This is the first version of the RMP.