VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Treatment of potassium deficiency, in particular if accompanied by hypochloraemic alkalosis

Supplementation of potassium as a part of parenteral nutrition

Potassium chloride concentrates are used as a medication to treat and prevent low potassium. They will be given by slow infusion by a drip into a vein. Potassium and chloride ions are important for maintaining the correct fluid balance in and around the body cells and tissues, and are involved in nerve and muscle function. Potassium chloride solution is given directly into the blood to restore the balance of potassium levels. It will also add water to tissues which are dehydrated.

Low levels of potassium in the blood (hypokalaemia) can affect this nerve and muscle functioning. The heart, as a muscle can be particularly affected. Normally, your blood potassium level is 3.6 to 5.2 millimoles (measure of amount-of-potassium concentration in blood) per litre (mmol/l). The frequency of hypokalaemia in the general population is difficult to estimate; however, probably fewer than 1% of people who are not taking medication have a blood potassium level lower than 3.5 mmol/l.

Potassium intake though diet varies from person to person. Although it is important to eat a diet rich in potassium, potassium can also be lost via urine, sweat and bowel movements. Therefore the risk of developing hypokalaemia can be due to a number of different factors. Up to 21% of hospitalised patients have serum potassium levels lower than 3.5 mmol/l, with 5% of patients exhibiting potassium levels lower than 3 mmol/l. Among elderly patients, 5% demonstrate potassium levels lower than 3 mmol/l. Of patients taking drugs to increase urine output (diuretics), 20-50% develop hypokalaemia. In patients taking these drugs hypokalaemia may be enhanced by another illness, such as heart failure or renal impairment.

VI.2.2 Summary of treatment benefits

Potassium chloride concentrates have been used for several decades and during this time have shown that they have a positive effect when used to treat fluid and electrolyte (especially potassium) imbalances. The use throughout these years have shown this medicine to be both safe and effective.

VI.2.3 Unknowns relating to treatment benefits

For several decades KCl conc. have been used as a potassium supplement given via a drip into a vein (parenteral) and therefore there are no unknowns relating to treatment benefits.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Elevated potassium level in the blood (hyperkalaemia)	In hyperkalaemia, the potassium levels in the blood are increased above the normal range. KCl concentrates contain potassium and they could increase the potassium level in the blood to outside the normal levels.	The infusion rate should be calculated by the healthcare professional depending on the blood electrolyte values, the acid base balance, the age and any other individual requirements of the patient. KCl conc. must not be used in patients with an abnormally high level of potassium in their blood (hyperkalaemia). Potassium supplements should be administered with caution in patients with heart disease particularly in patients taking a heart medication called digitalis. Potassium supplements should be administered with caution in patients with disorders that are frequently associated with hyperkalaemia e.g. ADDISON's disease (a rare chronic endocrine system disorder in which the adrenal glands do not produce sufficient steroid hormones) or sickle cell anaemia (a disorder of red blood cells). If a patient's kidneys are not functioning correctly, a kidney specialist will be contacted before the medicine is administered. Regular controls of the blood composition and ECG are necessary to detect any abnormalities.

Important potential risks

None.

Missing information

Pregnancy and lactation.

VI.2.5 Summary of risk minimisation measures by safety concern

Not applicable.

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.