

**sRMP**

**FI/H/866/001-2/DC**

**potassium chloride**

## **VI.2 Elements for a Public Summary**

### **VI.2.1 Overview of disease epidemiology**

KAL123 contains potassium chloride and is used in adults to treat low levels of potassium in the body and to prevent low levels of potassium, which may happen in connection with treatment with diuretics, so-called water-pills.

Less than 1% of people not taking medicine experience low levels of potassium, while up to half of those using diuretics may experience low levels of potassium. The elderly are more likely to experience low levels of potassium, as they more often use diuretics and have a potassium-poor diet.

When the level of potassium is only slightly lower than normal, there are often no symptoms. Symptoms of low potassium levels may include lack of energy, muscle cramps and disorders of heart rhythm.

### **VI.2.2 Summary of treatment benefits**

A low level of potassium is normally treated with oral potassium chloride supplements such as KAL123. In severe cases, potassium may be administered through a needle or tube inserted into a vein directly into the blood.

Potassium chloride supplements such as KAL123 are also used for preventing low level of potassium to occur in patients using diuretics.

### **VI.2.3 Unknowns relating to treatment benefits**

KAL123 is a well-established product which has been on the market since 1967. The product has been used in a broad spectrum of the population. However, the safety and efficacy of KAL123 in children have not been established.

## VI.2.4 Summary of safety concerns

### *Important identified risks*

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
<b>Hyperkalaemia (high level of potassium)</b>	When receiving potassium supplements the level of potassium in the body might become too high. This is called hyperkalaemia. Hyperkalaemia may cause a sense of pins and needles, muscle weakness, paralysis, confusion and heart problems. In the most severe cases hyperkalaemia might cause death. However, the symptoms usually resolve or improve after adjusting the dose or stopping treatment with potassium supplements.	The risk of developing hyperkalaemia while taking KAL123 is increased in patients who already have a high level of potassium, in patients with severe kidney disease, and patients with untreated Addison's disease. Other conditions such as adrenocortical insufficiency, acute dehydration, or severe burns may also increase the risk of hyperkalaemia. The level of potassium should be monitored in patients with cardiac or renal impairment.
<b>Obstruction, bleeding, ulceration or perforation of the digestive tract</b>	KAL123 prolonged release tablets may cause obstruction, bleeding, ulceration or perforation of the digestive tract. This may especially occur when taken with too little water or when administered to patients with a delayed passage through the digestive tract, as in bedridden or pregnant patients.	Taking the tablets with at least one glass of water and avoiding taking the tablets when lying down may prevent injury. Treatment with KAL123 should be stopped if severe nausea, vomiting or abdominal discomfort develops. KAL123 was developed as prolonged release tablets to decrease the risk of adverse events in the digestive tract.

### *Important potential risks*

No important potential risks have been identified for KAL123.

### *Missing information*

<b>Missing information</b>	<b>What is known</b>	<b>Preventability</b>
<b>Use in children</b>	KAL123 is a well established product, that has been used in a broad spectrum of the population. However, the safety and efficacy of KAL123 in children has not been established.	To ensure that the prescribers are aware of the fact that the safety and efficacy of KAL123 in children and adolescents aged below 18 years have not been established, a text is included in section 4.2 Posology and method of administration of the SmPC.

### **VI.2.5 Summary of additional 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 KAL123 can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

### **VI.2.6 Planned post authorisation development plan**

No post authorisation studies or development are planned.

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

Not applicable as this is the first RMP for this product.