VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Potassium is an important component of the body's cells and is important for the muscle and nerve function and the body's acid-alkaline balance. Potassium deficiency can occur with certain diseases and during treatment with different diuretics. 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.

Kaliumklorid Orifarm are intended to be used to prevent or treat low levels of potassium (hypokalaemia) in the blood. The most common reason causing potassium levels to fall is due to diuretic medications, the loss from the gastrointestinal tract, e.g. 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 is not specific to gender, population or pattern.

VI.2.2 Summary of treatment benefits

The correct potassium level is necessary for normal body functioning. Hypokalemia is a potentially life-threatening imbalance. The symptoms of hypokalemia are nonspecific and predominantly are related to muscular or cardiac function. Weakness and fatigue are the most common complaints. The muscular weakness that occurs with hypokalemia can manifest in protean ways (eg, dyspnea, constipation or abdominal distention, exercise intolerance). Rarely, muscle weakness progresses to frank paralysis. With severe hypokalemia or total body potassium deficits, muscle cramps and pain can occur with rhabdomyolysis. Occasionally, a patient may complain of worsening diabetes control or polyuria due to a recent onset of hyperglycemia or nephrogenic diabetes insipidus. Patients also may complain of palpitations. Psychological symptoms may include psychosis, delirium, hallucinations, and depression. Patients are often asymptomatic, particularly with mild hypokalemia. Symptoms that are present are often from the underlying cause of the hypokalemia rather than the hypokalemia itself.

Hypokalaemia is treated with both improved diets and/or potassium supplements.

Taking into account the published information on the use and dosage of Potassium chloride, it can be concluded that the use of this medicinal product in the proposed indications, i.e. treatment of hypokalaemia, and prevention of hypokalaemia caused by treatment with diuretics, and according to the dosage recommendations given in the SmPC is fully justified. Safety and efficacy of Potassium chloride in prevention and treatment of hypokalaemia in adults is sufficiently evident from its approved clinical use.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
• Hypersensitivity reactions	Hypersensitivity to the active substance or to any of the excipients is a known contraindication and patients with risk of hypersensitivity reactions should therefore not use kaliumklorid Orifarm.	There is no specific measure to prevent the risk. The risk is mentioned as a contraindication in the summary of Product Characteristics and patient information leaflet. The risk can be reduced by not allowing the product to be used in patients who are at risk of hypersensitivity reactions.
• Increased potassium levels in the blood in patients with kidney deficiency, untreated Addison's disease (non-functioning adrenal glands) or severe electrolyte imbalance (changes in the content of water or salts in your body). (Hyperkalaemia in patients with renal insufficiency, untreated Addison's disease or severe electrolyte imbalance.)	Severe electrolyte imbalance including hypercalcemia, hyperchloremia, hyperkalemia, or any other situations that may lead to hyperkalemia is a known contraindication and patients with this risk should therefore not use kaliumklorid Orifarm. Renal insufficiency is a known contraindication and patients with this risk should therefore not use kaliumklorid Orifarm. Untreated Addison's disease is a known contraindication and patients with this risk should therefore not use kaliumklorid Orifarm. Potassium chloride should be	There is no specific measure to prevent the occurrence of hyperkalaemia. The risks are mentioned as contraindications in the summary of Product Characteristics and patient information leaflet. The risk is mentioned as a warning in the summary of Product Characteristics and patient information leaflet. The risk can be reduced by not allowing the product to be used in patients who are at risk of hyperkalaemia.

Risk	What is known	Preventability
	administered with caution to patients with cardiac disease or conditions that can lead to hyperkalemia such as renal or adrenal insufficiency, acute dehydration or extensive tissue damage that occurs with severe burns. Serum potassium should be monitored in patients with cardiac or renal disorders. Hyperkalemia is an uncommon undesirable effect listed in section 4.8 of the SmPC.	
• Ulceration and/or perforation under conditions of narrowing of the esophagus, stomach and/or gut. (Ulceration and/or perforation under conditions of oesophageal stricture or obstructive disorders in the gastrointestinal tract.)	Oesophageal stricture or obstructive disorders in the gastrointestinal tract are known contraindication and patients with this risk should therefore not use kaliumklorid Orifarm. Potassium chloride should be administered with caution to patients where the passage through the gastrointestinal tract may be delayed. Treatment should be stopped if severe nausea, vomiting or abdominal pain occurs. Several gastrointestinal disorders are listed as undesirable effects in section 4.8 of the SmPC.	There is no specific measure to prevent the occurrence of ulceration and/or perforation under conditions of narrowing of the esophagus, stomach and/or gut. The risk is mentioned as a contraindication in the summary of Product Characteristics and patient information leaflet. The risk is mentioned as a warning in the summary of Product Characteristics and patient information leaflet. The risk can be reduced by not allowing the product to be used in patients who are at risk of ulceration and/or perforation under conditions of narrowing of the esophagus, stomach and/or gut.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
• Increased risk of gastrointestinal adverse effects under co-administration with anticholinergics/antimuscarinics	Anticholinergics/antimuscarinics delay gastric emptying and consequently may increase the risk of gastrointestinal adverse effects in patients receiving potassium chloride.
• Increased risk of increased potassium levels in the blood (hyperkalaemia) under co-administration with ACE inhibitors, ciclosporin and	Caution is required with concomitant use of potassium-sparing diuretics, ACE inhibitors and ciclosporin. Frequent determination of serum potassium should be performed during the treatment. Concomitant treatment with ACE inhibitors or potassium-sparing

Risk	What is known (Including reason why it is considered a potential risk)
potassium sparing diuretics.	diuretics increases the risk of hyperkalemia.
• Overdose	Overdose of potassium leads to the development of hyperkalemia, especially in patients with impaired renal function. Symptoms include weakness, mental confusion, paraesthesia of extremities, muscle weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac attack. ECG changes. Poisoning dose and Treatment is stated in the SmPC.

Missing information

Risk	What is known
Use in children	The drug should not be used in children, as there is no supporting evidence.

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 X can be found in the X's EPAR 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 as this is the initial Risk Management Plan.

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
	At time of authorisation dd/mm/yyyy	Identified Risks Potential Risks Missing information	
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