

 **17 March 2021**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**for**

**Kaliumklorid "Orifarm", prolonged-release tablets 1 g**

**0. D.SP.NO.**

28967

**1. NAME OF THE MEDICINAL PRODUCT**

Kaliumklorid "Orifarm"

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One prolonged-release tablet contains 1000 mg potassium chloride.

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Prolonged-release tablets

White, oval, biconvex tablet (17.5 × 9.1 × 8.0 mm)

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Hypokalaemia.

Prevention of hypokalaemia in connection with treatment with diuretics.

**4.2 Posology and method of administration**

Posology

*Adults:*

Prophylaxis:

1 prolonged release tablet 2 times daily.

In hypokalaemia, the dose should be individually adjusted according to the serum potassium values. Generally, the dose should be 2 tablets twice daily.

The serum potassium should be measured regularly in order to adjust the dosage according to the effect.

*Elderly:*

Dosing recommendations for older patients with normal renal function are the same as for adults with normal renal function. However, because older patients may have diminished renal function, dose adjustments may be required according to their renal function status (see Renal impairment below).

*Paediatric population:*

The safety and efficacy of the drug in children and adolescents aged below 18 years have not been established. No data is available.

*Renal impairment:*

Individually adjusted dose reduction is necessary in patients with mild to moderate renal impairment. Kaliumklorid "Orifarm" should not be used in patients with severe renal impairment (see sections 4.3 and 4.4).

Method of administration

The tablets should be swallowed whole with a glass of water and not in a lying down position.

Kaliumklorid "Orifarm" contains a white core that is excreted with the stools.

**4.3 Contraindications**

* Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
* Severe electrolyte imbalance including hyperkalemia, or any situation which might lead to hyperkalemia (see sections 4.4 and 4.5).
* Severe renal impairment (see section 4.4).
* Ulcer or obstruction of the gastrointestinal tract (see section 4.4).
* Untreated Addison’s disease (see section 4.4).

**4.4 Special warnings and precautions for use**

Potassium chloride should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalemia such as renal or adrenocortical insufficiency, acute dehydration or extensive tissue destruction as occurs with severe burns. Serum potassium should be monitored in patients with cardiac or renal impairment.

Potassium chloride should be administered with considerable care in elderly patients, as they are at increased risk for cardiac or renal impairment. Upper and lower gastrointestinal obstruction, bleeding, ulceration and perforation can occur, especially when potassium chloride is ingested with too little water or when administered to patients with a delayed passage through the gastrointestinal tract. Therefore, potassium chloride should be administered with caution to patients in whom passage through the gastrointestinal tract may be delayed, as in bedridden or pregnant patients (see section 4.6). Treatment should be discontinued if severe nausea, vomiting or abdominal discomfort develops.

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

Concomitant treatment with potassium-sparing diuretics (spironolactone, eplerenone, triamterene, and amiloride), angiotensin converting enzyme (ACE) inhibitors (e.g. captopril ,enalapril, lisinopril, perindopril, quinapril, ramipril, zofenopril), angiotensin II receptor antagonists (e.g. azilsartan, candesartan, eprosartan, irbesartan, losartan, tasosartan, telmisartan, valsartan), renin inhibitors (e.g. aliskiren), ciclosporin, tacrolimus, trimethoprim and drugs that contains potassium, such as the potassium salts of penicillin, increases the risk of hyperkalemia.

**4.6 Fertility, pregnancy and lactation**

Pregnancy

There are no or limited amount of data from the use of potassium chloride in pregnant women.

Potassium chloride should be given with caution to patients in whom passage through the gastrointestinal tract may be delayed, as in pregnant patients (see section 4.4). During pregnancy, Kaliumklorid "Orifarm" should only be used when the potential benefit justifies the potential risk.

Breast-feeding

Potassium is excreted in human milk, but at therapeutic doses of Kaliumklorid "Orifarm", no effects in the breast-fed newborns/infants are anticipated. Potassium chloride can be used during breast-feeding.

Fertility

There are no studies with potassium chloride regarding fertility.

**4.7 Effects on ability to drive and use machines**

No traffic warning.

Kaliumklorid "Orifarm" has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

The adverse reactions are identified from literature sources and spontaneous reporting.

Gastrointestinal disturbances can occur. Hyperkalemia and ulceration or bleeding of the gastrointestinal tract has been reported.
The undesirable effects are presented according to the MedDRA system organ classification and in the order of decreasing seriousness within each SOC. Due to limited amount of data, it is not possible to estimate the frequency of the undesirable effects.

|  |  |
| --- | --- |
| **Metabolism and nutrition disorders** |  |
|   | Hyperkalemia  |
| **Gastrointestinal disorders**  |  |
|  | Gastrointestinal perforationGastrointestinal hemorrhageGastric ulcerDuodenal ulcerOesophageal ulcerGastrointestinal obstructionGastrointestinal strictureDiarrheaVomitingAbdominal painNausea |
| **Skin and subcutaneous tissue disorders** |  |
|   | Rash\* |

\* Various types of rash reactions such as erythematous, maculopapular, paulosquamous, pruritic, and pustular rashes have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Lægemiddelstyrelsen

Axel Heides Gade 1

DK-2300 København S

Website: www.meldenbivirkning.dk

**4.9 Overdose**

Excessive doses of potassium lead to the development of hyperkalemia, especially in patients with impaired renal function. Symptoms include mental confusion, paraesthesia of the extremities, muscle weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest.
ECG changes are an important indicator for potassium toxicity.

Treatment should be according to local guidelines. The following should be considered: Gastric emptying, if necessary. ECG monitoring should be initiated. Insulin and glucose followed by oral or rectal administration of polystyrene sulphate. Intravenous infusion of sodium bicarbonate or intravenous injection of calcium chloride or calcium gluconate.

Toxic dose: 168 mmol.

Cardiac arrest may occur in young children after 60 mmol.

Severe symptoms are seen after approx. 3 mmol/kg body weight and death after 4-13 mmol/kg orally.

As there is no clear correlation between the degree of hyperkalaemia and the likelihood of life-threatening arrhythmias, the underlying medical conditions, including renal function, and concomitant drugs predisposing to abnormal intracellular/extracellular potassium balance and abnormal potassium excretion must be considered to ensure an individualised treatment.

**4.10 Legal status**

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**5. PHARMACOLOGICAL PROPERTIES**

**5.0 Therapeutic classification**

ATC-code: A 12 BA 01. Mineral supplements - Potassium.

**5.1 Pharmacodynamic properties**

Potassium chloride is released from the prolonged release tablet slowly during the passage through the small intestine, thus reducing the risk of side effects in form of unspecified ulcerations. The core is constructed of a white, soft lipid skeleton, which is excreted with faeces. The tablets are film-coated to make them easier to swallow and eliminate the bitter taste.

The potassium ion is an important cation in essential physiological processes such as maintenance of intracellular tonicity, transmission of nerve impulses, muscle contractions and maintenance of normal renal function.

Potassium is a normal dietary constituent and under steady state conditions the amount of potassium absorbed from the GI tract is equal to the amount excluded in the urine. The normal daily intake is 50-100 mEq per day. A decreased intake or increased potassium loss leads to symptoms of hypokalaemia.

**5.2 Pharmacokinetic properties**

Potassium is easily absorbed from the gastrointestinal tract. It enters the intracellular fluid to maintain a concentration of about 150 mEq/l and the normal range of concentration of potassium in the plasma is considered to be 3.5-5 mEq/l.

Excretion of potassium is primarily by the distal tubules of the kidneys.

The tablets are manufactured so that potassium chloride is released slowly in the gastrointestinal tract during 6-8 hours.

**5.3 Preclinical safety data**

There are no additional preclinical data of relevance for the safety evaluation than those mentioned in other sections of this Summary of Product Characteristics.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Stearyl alcohol

Ethylcellulose (E462)

Glycerol 85% (E422)

Magnesium stearate

Talc (E553b)

Hypromellose (E464)

Titanium dioxide (E171)

Saccharin sodium (E954)

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf-life**

5 years.

**6.4 Special precautions for storage**

No special precautions for storage.

**6.5 Nature and contents of container**

HDPE bottle with PP screw cap.

Pack sizes: 200, 210 or 220 tablets.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal and other handling**

No special requirements.

Any unused medicinal product or waste material should be disposed in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Orifarm Generics A/S

Energivej 15

5260 Odense S

**8. MARKETING AUTHORISATION NUMBER(S)**

64386

**9. DATE OF FIRST AUTHORISATION**

6 May 2015

**10. DATE OF REVISION OF THE TEXT**

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