
PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

PICORION 7.5 MG/ML DROPS, SOLUTION

ORION CORPORATION

DATE: 16-02-2015, VERSION 1

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Constipation is a common condition that affects people of all ages. It can mean that a person is not passing stools regularly or is unable to completely empty bowel. Constipation can also cause stools to be hard and lumpy, as well as unusually large or small. The severity of constipation varies from person to person. Many people only experience constipation for a short time, but for others, constipation can be a long-term (chronic) condition that causes significant pain and discomfort and affects quality of life. Constipation can occur in babies, children and adults. It is estimated that around one in every seven adults and up to one in every three children has constipation at some time. The condition affects twice as many women as men and is also more common in older adults and during pregnancy.

VI.2.2 Summary of treatment benefits

The active ingredient in Picorion, sodium picosulfate, forms a substance in the large intestine which increases the frequency of bowel movements. This also retains water in the large intestine. This softens the stools and makes bowels movements easier. In many cases, diet and lifestyle changes are recommended as the first treatment for constipation. Laxatives such as Picorion are used for the short-term treatment of severe constipation when e.g. dietary changes are considered insufficient. The safety and efficacy of sodium picosulfate for the short-term treatment of severe constipation has been established.

VI.2.3 Unknowns relating to treatment benefits

There are no adequate studies on the use of sodium picosulfate in pregnant women. Long-time experience has not indicated any harmful effects when sodium picosulfate is used during pregnancy.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Use in patients with certain gastrointestinal conditions	Use of laxatives such as sodium picosulfate may worsen certain gastrointestinal conditions such as inflammatory bowel diseases.	Picorion must not be used: <ul style="list-style-type: none">- if patient has a blocked bowel- if patient has a severe painful and/or febrile abdominal condition (e.g., appendicitis), which may be associated with nausea and vomiting- if patient has bowel inflammation.

Risk	What is known	Preventability
		Use of Picorion is not recommended following abdominal surgery.
Use in patients with severe fluid imbalance (dehydration)	Use of laxatives such as sodium picosulfate may cause diarrhoea and affect fluid and electrolyte balance.	Picorion must not be used if patient has severe fluid imbalance.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Prolonged or excessive use	As with all laxatives, Picorion should not be taken on a continuous daily basis or for long periods without investigating the cause of constipation. Excessive long-term use may lead to fluid imbalance and lower blood potassium concentration. Picorion must be used according to dosage instructions.
Use in children under 12 years of age	Use of Picorion is not recommended in children under 12 years of age except when supervised by a doctor or as directed by a doctor since small children may be more susceptible to the effects of sodium picosulfate.

Missing information

Risk	What is known
Use during pregnancy	There are no adequate studies on the use of sodium picosulfate in pregnant women. Long-time experience has not indicated any harmful effects when sodium picosulfate is used during pregnancy. If patient is pregnant or breast-feeding, thinks she may be pregnant or is planning to have a baby, she should ask doctor or pharmacist for advice before taking Picorion.

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 Picorion 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 (if applicable)***

Not applicable.

VI.2.7 ***Summary of changes to the risk management plan over time***

Not applicable.