PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

POSIREX HONEY-LEMON AND POSIREX MINT LOZENGES

ORION OYJ

DATE: 30-01-2017, VERSION 1.2

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Posirex is indicated for sore throat and disinfection of mouth and pharynx.

Sore throat is often caused by infection in the throat caused by microbes (bacteria or viruses). Also nasal obstruction can induce soreness and itching of the throat because mouth breathing makes the throat dry.

The exact prevalence of sore throat is difficult to assess but it is a common condition. On average an adult will experience sore throat 2-3 times per year while children are more susceptible for sore throat due to their immature immune system.

VI.2.2 Summary of treatment benefits

Posirex helps to relieve discomfort and soreness of mouth and throat infections. It contains two antiseptics, amylmetacresol and dichlorobenzyl alcohol, which act against microbes that cause throat infections. Combination of these two antiseptics have been used to relieve sore throat since the late 1950s.

Sucking Posirex lozenges also lubricates and soothes the throat. Increased saliva production may also help to flush the offending microbes from the throat surface.

VI.2.3 Unknowns relating to treatment benefits

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VI.2.4 Summary of safety concerns

Important identified risk

Risk	**What is known**	**Preventability**
Hypersensitivity reactions	People that are hypersensitive to one of the components of the products may encounter allergic reactions. Hypersensitivity reactions may include rash, burning sensation of mouth or pharynx, tingling, itching, stinging or swelling.	People that are hypersensitive to any of the components of the product should not use Posirex.

Missing information

Risk	What is known
Safety of use during pregnancy and breastfeeding	The safety of Posirex during pregnancy and lactation has not been fully established, but is not considered to constitute a hazard during these periods. However, as for every medicinal product, caution should be administered when using during pregnancy and breastfeeding.

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 Posirex 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

Not applicable.

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

Not applicable.