Part VI: Summary of the risk management plan

Summary of risk management plan for Fluoride 2800 ppm Toothpaste, Fluoride 5000 ppm Toothpaste, Fluorid Morningside 5mg/g Toothpaste, Natriumfluorid Morningside 5mg/g Toothpaste, Natriumfluoridi Morningside 5 mg/g hammastahna 5mg/g Toothpaste and Natriumfluorid Morningside 5 mg/g tannpasta 5mg/g Toothpaste (herein after referred to as Sodium fluoride).

This is a summary of the risk management plan (RMP) for Sodium fluoride The RMP details important risks of Sodium fluoride, how these risks can be minimised, and how more information will be obtained about sodium flouride's risks and uncertainties (missing information).

Sodium fluoride's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how fluoride toothpaste should be used.

I. The medicine and what it is used for

Sodium fluoride is used for the prevention of dental caries in adolescents and adults, particularly amongst patients at risk from multiple caries (coronal and / or root caries) and adolescents and children aged ten years or more.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Sodium fluoride together with measures to minimise such risks and the proposed studies for learning more about Sodium fluoride risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken, as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Sodium fluoride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

List of important risks and missing information	
Important identified risks	• Use in children aged less than 10 years • Fluorosis • Overdose, particularly in patients who swallow large amount of toothpaste or are receiving other supplements
Important potential risks	• None
Missing information	• Use during pregnancy and breast-feeding and effects on fertility (5000 ppm Fluoride Toothpaste)

II.B Summary of important risks

The safety information in the proposed Product Information is based on the most updated current scientific knowledge .

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of sodium fluoride.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for sodium fluoride.