Part VI: Summary of the risk management plan for Orilaxal

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

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

I. The medicine and what it is used for

Orilaxal is authorised for use to resolve constipation. It contains sodium picosulphate as the active substance and it is given orally as oral drops.

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

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

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish Medicines Agency.
- Information about use and warnings are listed on the outer package of the product.
- The medicine's is sold without prescription but for use in children a doctor should be consulted.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Orilaxal is not yet available, it is listed under `missing´ information' below

II.A List of important risks and missing information

Important risks of Orilaxal are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Orilaxal. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Orilaxal.

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

There are no studies required for Orilaxal.