

# Part VI: Summary of the risk management plan for Colestyramin Orifarm

This is a summary of the risk management plan (RMP) for Colestyramin Orifarm. The RMP details no important risks of Colestyramin Orifarm and no missing information.

The Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients about how Colestyramin Orifarm should be used.

## I. The medicine and what it is used for

Colestyramin Orifarm is authorised for treatment of high levels of cholesterol in the blood, to reduce itching caused by bile salts and to treat diarrhea caused by excess levels of bile acids in the intestine. (see SmPC for the full indication). It contains colestyramine as the active substance and it is given as an oral solution.

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

There are no important risks of Colestyramin Orifarm and no missing information.

- 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.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

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

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

### II.A List of important risks and missing information

Important risks of Colestyramin Orifarm 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 Colestyramin Orifarm. 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 Colestyramin Orifarm.

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

There are no studies required for Colestyramin Orifarm.