Part VI: Summary of the risk management plan for Tobramethason

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

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

I. The medicine and what it is used for

Tobramethason is authorised for prevention and treatment of inflammation and prevention of infection associated with cataract surgery in adults and children aged 2 years and older (see SmPC for the full indication). It contains tobramycin and dexamethasone as the active substances and it is given as eye drops.

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

There are no important risks of Tobramethason 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 and Swedish 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 Tobramethason is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tobramethason 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 Tobramethason. 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

Summary of safety concerns	
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 Tobramethason.

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

There are no studies required for Tobramethason.