Summary of risk management plan for Tobramycin PARI (tobramycin)

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

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

This summary of the RMP for Tobramycin PARI should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tobramycin PARI's RMP.

I. The medicine and what it is used for

Tobramycin PARI is authorised for the management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis (CF) (see SmPC for the full indication). It contains tobramycin as the active substance and it is administered by inhalation.

Further information about the evaluation of Tobramycin PARI's benefits can be found in Tobramycin PARI's EPAR, including its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/tobramycin-pari.

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

Important risks of Tobramycin PARI, together with measures to minimise such risks and the proposed studies for learning more about Tobramycin PARI's 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 as 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.

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

II.A List of important risks and missing information

Important risks of Tobramycin PARI are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be administered safely. 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 Tobramycin PARI. 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	Nephrotoxicity Ototoxicity
Missing information	Use during pregnancy or lactation

II.B Summary of important risks

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

Important potential risk: Nephrotoxicity	
Risk minimisation measures	Routine risk communication: - SmPC section 4.4 - SmPC section 4.5 - SmPC section 4.6 - SmPC section 4.8 - SmPC section 4.9 - SmPC section 5.3 Routine risk minimisation activities recommending specific clinical measures to address the risk: - Recommendation for renal function monitoring is included in SmPC section 4.4 - Recommendation for serum tobramycin concentration monitoring is included in SmPC section 4.4
Important potential risk: Ototoxicity	
Risk minimisation measures	Routine risk communication: - SmPC section 4.4 - SmPC section 4.5 - SmPC section 4.6 - SmPC section 4.8 - SmPC section 4.9 - SmPC section 5.3

	Routine risk minimisation activities recommending specific clinical measures to address the risk: - Recommendation for auditory functioning monitoring and initial audiological assessment is included in SmPC section 4.4 - Recommendation for serum tobramycin concentration monitoring is included in SmPC section 4.4
Missing information: Use during pregnancy or lactation	
Risk minimisation measures	Routine risk communication: - SmPC section 4.6 - PL section 2 Other routine risk minimisation measures beyond the Product Information: - Follow-up questionnaires

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 Tobramycin PARI.

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

There are no studies required for Tobramycin PARI.