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Public Risk Management Plan (RMP) Summary

TOBI Podhaler (Tobramycin)
Inhalation powder, capsules

Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of **TOBI Podhaler** is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of TOBI Podhaler in Switzerland is the “Arzneimittelinformation/Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Viatris Pharma GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of TOBI Podhaler.

Summary of Risk Management Plan for TOBI Podhaler (tobramycin)

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

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

This summary of the RMP for TOBI Podhaler should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all 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 TOBI Podhaler's RMP.

I. The Medicine and What it is Used For

TOBI Podhaler is authorised for the suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis. It contains tobramycin as the active substance and it is given by inhalation (using the Podhaler device) route of administration.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of TOBI Podhaler, together with measures to minimise such risks and the proposed studies for learning more about TOBI Podhaler'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 so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

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

II.A List of Important Risks and Missing Information

Important risks of TOBI Podhaler are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 TOBI Podhaler. 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/use in special patient populations etc.).

Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	None
Important Potential Risks	None
Missing Information	None

II.B Summary of Important Risks

Not applicable

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 TOBI Podhaler.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for TOBI Podhaler.