PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

TOVIAZ (FESOTERODINE)

MARKETING AUTHORIZATION NUMBER 58743

Sustained-release tablets, 4 mg / 8 mg

Document Version: 1.0

Document Date: 07 December 2023

Based on Part VI of EU RMP version 10, dated 19 March 2021 and Swiss RMP-Addendum version 1.0, dated 21 September 2023

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LIST OF ABBREVIATIONS

EMA	European Medicines Agency
EPAR	European Public Assessment Report
EU	European Union
NDO	Neurogenic Detrusor Overactivity
PL	Patient Leaflet
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics (Europe)

OVERVIEW

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 for fesoterodine 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 fesoterodine in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic. Pfizer is fully responsible for the accuracy and correctness of the content of the published RMP summary of fesoterodine.

SUMMARY OF RISK MANAGEMENT PLAN FOR FESOTERODINE

Summary of the risk management plan for Toviaz

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

Toviaz's SmPC and its PL give essential information to healthcare professionals and patients on how Toviaz should be used.

This summary of the RMP for Toviaz should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the EPAR.

I. The Medicine and What it is Used for

Toviaz is authorised for treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur in patients with overactive bladder syndrome (see SmPC for the full indication). It contains fesoterodine as the active substance and it is given by oral route of administration.

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

In Switzerland Toviaz is also indicated for the treatment of neurogenic detrusor overactivity (NDO; for example, in patients with spina bifida or meningomyelocele) in paediatric patients 6 years of age and older with a body weight greater than 25 kg.

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

There are no important identified or potential risks for Toviaz and no missing information. Routine risk minimisation activities, which include the use of SmPC and PL for these products are sufficient to manage the product.

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

In the frame of the registered paediatric indication in Switzerland, Swissmedic has requested the addition of 1 important potential risk and 1 missing information to the list of the safety concerns (see below).

II.A. List of Important Risks and Missing Information

Important risks of Toviaz 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 Toviaz. 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).

Table 1. List of Important Risks and Missing Information

Important Identified Risks	None
Important Potential Risks	Cognitive and psychomotor impairment in paediatric patients*
Missing Information	Safety of long-term use in children*

* Important potential risk as requested by Swissmedic. Applies to Switzerland only.

II.B. Summary of Important Risks

Table 2. Important Potential Risk: Cognitive and psychomotor impairment in paediatric patients*

Evidence for linking the risk to the medicine:	Clinical trial data, post-marketing safety data, Published literature, SmPC.
Risk factors and risk groups:	No specific risk factors associated with fesoterodine usage have been identified.
Risk minimisation measures:	Routine risk minimisation measures: See section “Warnings and precautions” of the Swiss Information for Professionals. Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

* Important potential risk as requested by Swissmedic. Applies to Switzerland only.

Table 3. Missing Information: Safety of long-term use in children*

Risk minimisation measures:	Routine risk minimisation measures: See section "Warnings and precautions" of the Swiss Information for Professionals. Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

* Missing information as requested by Swissmedic. Applies to Switzerland only.

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 this product.

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

There are no studies required for fesoterodine.