

**SWISS SUMMARY OF THE RISK MANAGEMENT PLAN (RMP) FOR**

**ZERBAXA<sup>®</sup>**

**(Ceftolozane/Tazobactam)**

Active substance(s): Ceftolozane/Tazobactam

Product(s) concerned: ZERBAXA

Based on EU RMP 2.1

Market Authorisation Holder: MSD Merck Sharp & Dohme AG, Lucerne

March 2020

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 minimize them.

The RMP summary of ZERBAXA 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 authorisation.

Please note that the reference document which is valid and relevant for the effective and safe use of ZERBAXA in Switzerland is the 'Arzneimittelinformation/Information sur le médicament' (see [www.swissmedicinfo.ch](http://www.swissmedicinfo.ch)) approved and authorized by Swissmedic. MSD Merck Sharp & Dohme AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of ZERBAXA.

## **I. The Medicine and What it is Used for**

ZERBAXA is authorised for the treatment of complicated bacterial infections (those that are difficult to treat) affecting the organs inside the abdomen (belly) or the kidneys and structures that carry urine (the urinary tract) or the lungs (see 'Arzneimittelinformation/Information sur le médicament' for the full indication). It contains ceftolozane and tazobactam as the active substances and it is given by intravenous infusion.

## **II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks**

Important risks of ZERBAXA, together with measures to minimise such risks and the proposed studies for learning more about ZERBAXA'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 ‘Arzneimittelinformation/Information sur le médicament’ 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 patient (e.g. with or without prescription) can help to minimise its risks.

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

In addition to these measures, information about adverse reactions 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 ZERBAXA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 ZERBAXA. 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).

Since its approval in the EU in 2015 and Switzerland in 2016, the safety profile for ZERBAXA has been well characterised. There are no studies planned or warranted to further characterise any identified or potential risk that would alter the established risk-benefit profile for ZERBAXA. There are also no additional risk minimisation activities planned or warranted beyond communication of the safety profile in the ‘Arzneimittelinformation/Information sur le médicament’. As such, there are no important safety concerns (important identified or potential risks or missing information) for which prospective additional risk management is

planned. Therefore, there are no important identified or potential risks or missing information associated with ZERBAXA to be addressed in the RMP.

In conclusion, continued spontaneous safety surveillance and the safety information available in the Product Information are considered sufficient to monitor the safety profile and to provide routine risk minimisation for ZERBAXA.

**Table II.A.1: List of Important Risks and Missing Information**

<b>List of Important Risks and Missing Information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

## **II.B Summary of Important Risks**

The safety information for ZERBAXA is provided in the Product Information.

There are no identified risks, potential risks, or missing information in this RMP.

## **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 ZERBAXA.

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

There are no studies required for ZERBAXA.