Swiss Risk Management Plan Summary

VABOREM® (Meropenem/Vaborbactam)

Document Version 2.0 (26.03.2024)
Based on EU RMP VABOREM version 2.1 (signed on 13.09.2023)

Marketing authorization holder: A. Menarini GmbH, Switzerland
Vaborem® powder for concentrate for solution for infusion

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

SUMMARY OF RISK MANAGEMENT PLAN FOR VABOREM (MEROPENEM/VABORBACTAM)

This is a summary of the risk management plan (RMP) for Vaborem. The RMP details important risks of Vaborem, how these risks can be minimised, and how more information will be obtained about Vaborem's risks and uncertainties (missing information).
Vaborem's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vaborem should be used.

This summary of the RMP for Vaborem 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 European Public Assessment Report (EPAR).
Important new concerns or changes to the current ones will be included in updates of Vaborem's RMP.

I. The medicine and what it is used for

Vaborem is authorised for treatment of the following infections in adults:
- Complicated urinary tract infection (cUTI), including pyelonephritis
- Complicated intra-abdominal infection (cIAI)
- Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)
- Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Vaborem is also indicated for the treatment of infections due to bacterial organisms in adult patients with limited treatment options (see SmPC for the full indication). It contains meropenem and vaborbactam as the active substances and it is given by intravenous administration.

Further information about the evaluation of Vaborem's benefits can be found in Vaborem's EPAR, including in its plain-language summary, available on the European Medicines Agency website, under the medicine's webpage link to the EPAR summary landing page

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

Important risks of Vaborem, together with measures to minimise such risks and the proposed studies for learning more about Vaborem'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 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 Vaborem 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 Vaborem. 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);

List of important risks and missing information	
Important Identified Risks	None
Important Potential Risks	None
Missing Information	None

II.B. *Summary of important risks*

Important identified risk, potential risk or missing information: None	
Evidence for linking the risk to the medicine	Not applicable
Risk factors and risk groups	Not applicable
Risk minimisation measures	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 Vaborem.

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

There are no studies required for Vaborem.