

Public Summary SwissPAR dated 29 November 2021

Vaborem[®] (active substances: meropenem trihydrate, vaborbactam)

First authorisation in Switzerland: 1 July 2021

Medicinal product (antibiotic) for the treatment of certain bacterial infections in adults

About the medicinal product

Vaborem contains the active substances meropenem (as meropenem trihydrate) and vaborbactam. It is supplied as a powder for concentrate for solution for infusion that is injected into the veins.

Vaborem is a prescription-only medicine used for treating the following infections in adults, if it has been confirmed, or if it is strongly suspected, that the respective infection is caused by sensitive bacteria:

- Urinary tract infections (cUTI), including pyelonephritis (inflammation of the renal pelvis)
- Intra-abdominal infection¹ (cIAI)

- Hospital-acquired pneumonia² (HAP) including ventilator-associated pneumonia³ (VAP)

Vaborem is also used for the treatment of patients with bacteraemia⁴ that occurs in association with, or is suspected to be associated with, any of the infections listed above.

In order to prevent the development of resistance, the medicinal product may be used for treating the listed infections only if other antibiotics recommended for the initial treatment of these infections are not appropriate.

Mode of action

Vaborem consists of the two active substances meropenem and vaborbactam, which act in different ways. Meropenem is bactericidal (kills bacteria) and has long

been authorised in Switzerland as a single medicinal product.

Vaborbactam has no antibacterial effect, but inhibits beta-lactamases (bacterial enzymes) that are capable of inactivating

¹ Intra-abdominal infections (IAIs): IAIs are infections in the abdomen.

² Hospital-acquired pneumonia (HAP): Hospital-acquired pneumonia is a pneumonia that has occurred in association with a medical procedure, e.g. during a hospital stay

³ Ventilation-associated pneumonia (VAP): VAP is a pneumonia that has occurred in association with intubation or artificial ventilation.

⁴ Bacteraemia: An infection of the blood associated with infections of the abdomen, urinary tract or lung.

meropenem. By inhibiting these beta-lactamases, vaborbactam allows meropenem to exert its effect.

Use

Vaborem is a prescription-only medicine supplied as a powder for the preparation of a concentration for solution for infusion. The usual dosage is 2 g meropenem with 2 g vaborbactam every 8 hours. If renal function

is impaired, with a CrCL⁵>40 mL/min, the dose must be adjusted.

The infusion time is 3 hours and the duration of treatment varies between 5 to 14 days depending on the type and site of the infection.

Efficacy

The available evaluation reports and the corresponding product information texts issued by the European (EMA) and American (FDA) regulatory authorities were used as the basis for evaluating the efficacy data for this authorisation.

The evaluation focused on the requested indications of complicated intra-abdominal infection (cIAI) and hospital-acquired pneumonia (HAP), including ventilation-associated pneumonia (VAP), as well as the treatment of infections due to aerobic Gram-negative bacteria in patients with limited treatment options.

The efficacy in these indications was substantiated by study "506", in which Vaborem was compared with the best currently available treatment.

The primary efficacy endpoints were defined according to the respective indication.

A statistical analysis was not performed due to the limited number of patients per indication. The overall results summarised for all types of infection (in 322 patients) indicate a benefit for Vaborem in the treatment of infections caused by carbapenemase-producing enterobacteria.

Precautions, undesirable effects & risks

Vaborem must not be used in those who are hypersensitive to the active substances or any of the excipients.

Like all medicines, Vaborem can produce side effects, although not necessarily in everyone.

The most common (affecting more than 1 in 10 patients) undesirable effects of Vaborem are headache, diarrhoea, nausea and phlebitis (superficial inflammation of the veins at the infusion site).

Serious and occasionally fatal hypersensitivity reactions have been reported for meropenem and/or Vaborem (meropenem/vaborbactam). Before initiating therapy with Vaborem, the doctor should inquire carefully about previous hypersensitivity reactions to beta-lactam antibiotics. Severe skin reactions during treatment with meropenem have also been reported.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

⁵ CrCL: CrCL is the creatinine clearance. The creatinine clearance test evaluates kidney function.

Why the medicinal product has been authorised

The number of infections caused by certain bacteria that are resistant to currently available antibiotics is increasing worldwide. Not only do these infections involve longer hospital stays and higher costs in healthcare, they are also associated with increased mortality. Since the options for treating such infections are very limited, there is a need for effective treatments for infections caused by resistant bacteria.

In the treatment of cUTI, cAI, HAP/VAP caused by carbapenemase-producing enterobacteria or bacteraemia associated with one of these infections, Vaborem can be assumed to be effective and safe on the basis of the existing efficacy and safety data for

meropenem therapy on its own and the available preclinical and pharmacokinetic data for the combination product Vaborem. In view of the limited number of patients with these infections participating in the studies, this could not be entirely confirmed by efficacy and safety data.

Taking all the risks and precautions into account, and based on the available data, the benefits of Vaborem in treating the infections described above outweigh the risks. Swissmedic has therefore authorised the medicinal product Vaborem with the active substances meropenem and vaborbactam for the listed indications.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Vaborem®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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