# Summary of risk management plan for Recarbrio (imipenem and cilastatin and relebactam)

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

The summary of product characteristics (SmPC) of Recarbrio and its package leaflet give essential information to healthcare professionals and patients on how Recarbrio should be used.

This summary of the RMP for Recarbrio 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 the RMP for Recarbrio.

## I. The Medicine and What it is Used For

Recarbrio is authorised for the treatment of infections due to hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults, and bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP in adults, and infections due to aerobic gram-negative organisms in adults with limited treatment options (see SmPC for the full indication). It contains imipenem, cilastatin, and relebactam as active substances and it is given by powder for solution for infusion.

Further information about the evaluation of the benefits of Recarbrio can be found in the EPAR for Recarbrio, 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/recarbrio.

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

Risks associated with Recarbrio will be subject to the routine risk minimisation measures outlined below:

- Specific information about CNS events (including seizures, confusional states and dizziness), hypersensitivity reactions, *Clostridioides difficile*- related pseudomembranous enterocolitis, and drug-drug interactions with valproic acid or divalproex sodium which have been observed in the post-marketing experience with the imipenem/cilastatin components of Recarbrio, are described in the SmPC. This includes a contraindication for use in patients with history of severe hypersensitivity to any component of the product, and information in Special Warnings and Precautions for use and the Adverse Reactions sections of package leaflet and SmPC addressed to patients and healthcare professionals, respectively, with advice on correct use and appropriate dosing for patients with renal impairment.

- 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 in aggregate periodic benefit-risk evaluation reports 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 Recarbrio are risks that need special risk management activities to investigate further 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 Recarbrio. 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 II.A.1: List of Important Risks and Missing Information**

| List of Important Risks and Missing Information | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

## II.B Summary of Important Risks

There are no important identified risks, important potential risks or missing information for Recarbrio.

## 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 Recarbrio.

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

There are no studies required for Recarbrio.