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Recarbrio (*imipenem / cilastatin / relebactam*)

An overview of Recarbrio and why it is authorised in the EU

What is Recarbrio and what is it used for?

Recarbrio is an antibiotic for treating adults with the following infections:

- lung infections caught in hospital (hospital-acquired pneumonia), including ventilator-associated pneumonia (pneumonia caught while on a ventilator, which is a machine that helps a patient to breathe);
- infection that has spread into the blood (bacteraemia) as a likely complication of hospital-acquired pneumonia or ventilator-associated pneumonia;
- infections caused by bacteria classed as aerobic Gram-negative bacteria when other treatments might not work.

Official guidance on the appropriate use of antibiotics should be considered when using the medicine.

Recarbrio contains the active substances imipenem, cilastatin and relebactam.

How is Recarbrio used?

Recarbrio can only be obtained with a prescription and it should be used only after consulting a doctor with experience of managing infectious diseases.

Recarbrio is given by infusion (drip) into a vein over 30 minutes. It is given every 6 hours for 5 to 14 days, depending on the nature of the infection.

For more information about using Recarbrio, see the package leaflet or contact your doctor or pharmacist.

How does Recarbrio work?

One of the active substances in Recarbrio, imipenem, kills bacteria and the other two, cilastatin and relebactam, increase imipenem's effectiveness in different ways.

Imipenem interferes with bacterial proteins that are important for building the bacterial cell wall. This results in defective cell walls that collapse and cause the bacteria to die. Imipenem is quickly broken down by the kidneys and the cilastatin in Recarbrio prevents this breakdown and so allows imipenem

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

to work for longer. The third active substance, relebactam, blocks enzymes in the bacteria called beta-lactamases. These enzymes break down antibiotics such as imipenem and stop them working.

What benefits of Recarbrio have been shown in studies?

In a main study in 47 adults with infections caused by Gram-negative bacteria, 71% of patients treated with Recarbrio had a favourable outcome (based on their symptoms and test results) compared with 70% of patients treated with another combination (colistin, imipenem and cilastatin). Patients in this study had serious infections that were resistant to treatment with imipenem plus cilastatin. Patients were treated for hospital-acquired pneumonia, complicated intra-abdominal infection (infection that has spread in the belly with swelling and build-up of pus) and complicated urinary tract infection (infection extending beyond the bladder into the kidneys).

In a second main study involving 537 patients with hospital-acquired or ventilator-associated pneumonia, 61% of patients treated with Recarbrio were cured (assessed 7 to 14 days after the end of treatment) compared with 56% of patients treated with piperacillin and tazobactam (another antibiotic combination).

What are the risks associated with Recarbrio?

The most common side effects with Recarbrio (which may affect up to 1 in 10 people) are diarrhoea and blood test results showing disturbances in liver enzymes (suggesting stress on the liver).

Recarbrio must not be used in patients who are hypersensitive (allergic) to imipenem and other carbapenem antibiotics (such as ertapenem and meropenem) or in patients who have had a severe allergic reaction to the broader class of beta-lactam antibiotics (such as penicillins and cephalosporins).

For the full list of side effects and restrictions of Recarbrio, see the package leaflet.

Why is Recarbrio authorised in the EU?

There were too few patients in the main study of infections caused by Gram-negative bacteria to show conclusively that Recarbrio is effective against bacteria that have become resistant to imipenem. However, studies on how the medicine works in the body provided more evidence of its effectiveness. Recarbrio can therefore be useful when there is limited choice of treatment for bacterial infections resistant to imipenem and other carbapenem antibiotics.

The study in patients with hospital-acquired or ventilator-associated pneumonia found Recarbrio at least as effective as the antibiotic combination piperacillin with tazobactam. The European Medicines Agency noted that imipenem plus cilastatin is already authorised for treating bacteraemia linked to hospital-acquired or ventilator-associated pneumonia.

Recarbrio's side effects, which are similar to those of imipenem with cilastatin, are acceptable.

The Agency therefore decided that Recarbrio’s benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Recarbrio?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Recarbrio have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Recarbrio are continuously monitored. Side effects reported with Recarbrio are carefully evaluated and any necessary action taken to protect patients.

Other information about Recarbrio

Recarbrio received a marketing authorisation valid throughout the EU on 13 February 2020.

Further information on Recarbrio can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/recarbrio.

This overview was last updated in 11-2020.