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Xerava (*eravacycline*)

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

What is Xerava and what is it used for?

Xerava is an antibiotic used to treat complicated intra-abdominal (belly) infections (cIAI) in adults. 'Complicated' means that the infection is difficult to treat because it has spread to the abdominal space.

Xerava contains the active substance eravacycline.

How is Xerava used?

Xerava can only be obtained with a prescription and prescribers should take into account official guidance on the use of antibiotics.

Xerava is given by infusion (drip) into a vein over one hour. The medicine is given once every 12 hours for at least 4 days and up to 14 days. The dose depends on the patient's bodyweight, and may be increased if the patient is also taking a type of medicine called a 'strong CYP3A4 inducer'.

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

How does Xerava work?

The active substance in Xerava, eravacycline, belongs to a group of antibiotics called tetracyclines. Tetracyclines work by binding to and blocking part of the cell machinery in bacterial cells that is involved in making proteins. This leads to death of the bacteria causing the infection.

What benefits of Xerava have been shown in studies?

Xerava was shown to be as effective as alternative antibiotics in 2 main studies of adults with cIAIs. The main measure of effectiveness in both studies was whether the infection was cured.

In the first study involving 538 patients, Xerava was compared with ertapenem (another antibiotic). After around a month, 87% of patients treated with Xerava were cured of their infection, compared to 89% of patients treated with ertapenem.

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In the second study involving 499 patients, Xerava was compared with meropenem (another antibiotic). After around a month, 92% of patients treated with Xerava and 92% of patients treated with meropenem were cured of their infection.

What are the risks associated with Xerava?

The most common side effects with Xerava (which may affect up to 1 in 10 people) are thrombophlebitis (inflammation of veins caused by a blood clot), phlebitis (inflammation of a vein), nausea (feeling sick), vomiting and reactions at the site of the infusion including reddening of skin, reduced sense of touch and pain. For the full list of side effects of Xerava, see the package leaflet.

Xerava must not be used in patients who are hypersensitive (allergic) to any of the ingredients of the medicine or to other tetracycline antibiotics.

Why is Xerava authorised in the EU?

Xerava is as effective as alternative antibiotics in treating infections caused by various types of bacteria and produced high cure rates. Xerava's safety profile was considered acceptable. Therefore the European Medicines Agency decided that Xerava'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 Xerava?

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

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

Other information about Xerava

Xerava received a marketing authorisation valid throughout the EU on 20.09.2018.

Further information on Xerava can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.