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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 adolescents from 12 years of age who weigh at least 50 kg and 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. It is given once every 12 hours for at least 4 days and up to 14 days. The dose depends on the patient's weight, 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 attaching to and blocking part of the cell machinery in bacteria that is involved in making proteins. This leads to the 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 involving adults with cIAIs. The main measure of effectiveness in both studies was whether the infection was cured.

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

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

The company also provided data on how the medicine behaves in the body in children aged 8 to 17 years with a suspected or confirmed bacterial infection. These data were inconclusive and it was therefore not possible to establish an appropriate dose for children below 12 years of age or for adolescents from 12 years of age weighing less than 50 kg.

What are the risks associated with Xerava?

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

The most common side effects with Xerava in adults (seen in up to 1 in 10 people in clinical trials) include nausea (feeling sick), vomiting, phlebitis (inflammation of a vein) at the site of infusion, phlebitis, thrombosis (formation of blood clots in the blood vessels) at the infusion site, diarrhoea, reactions at the site of the infusion including reddening of skin and reduced sense of touch and pain, thrombophlebitis (inflammation of veins caused by a blood clot), hyperhidrosis (excessive sweating) and headache.

The most common side effects with Xerava in children (seen in more than 1 in 10 people in a clinical trial) include nausea, vomiting, headache and hyperhidrosis.

Xerava must not be used in patients who are hypersensitive 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 achieves high cure rates. Since Xerava is expected to behave in a similar way in adolescents from 12 years of age and weighing at least 50 kg as in adults, its use can be extended to this population. Xerava's safety profile is considered acceptable. The European Medicines Agency therefore 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 September 2018.

Further information on Xerava can be found on the Agency's website: ema.europa.eu/medicine/human/EPAR/xerava.

This overview was last updated in 12-2025.