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Ertapenem SUN (*ertapenem*)

An overview of Ertapenem SUN and why it is authorised in the EU

What is Ertapenem SUN and what is it used for?

Ertapenem SUN is an antibiotic. It is used in adults and children over 3 months of age to treat:

- infections within the abdomen;
- community-acquired pneumonia (infection of the lungs caught away from hospital);
- gynaecological infections;
- foot infections in diabetes patients.

Ertapenem SUN is also used in adults to prevent infection after colorectal surgery (surgery in the lower part of the bowel, including the rectum).

Ertapenem SUN is used when the bacteria that cause the infection are likely to be killed by the antibiotic. Before using Ertapenem SUN, doctors should consider official guidance on the appropriate use of antibiotics.

Ertapenem SUN is a 'generic medicine'. This means that Ertapenem SUN contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Invanz. For more information on generic medicines, see the question-and-answer document here.

Ertapenem SUN contains the active substance ertapenem.

How is Ertapenem SUN used?

Ertapenem SUN is available as a vial containing a powder which is dissolved before use to make up a solution for infusion (drip) into a vein. It is infused over 30 minutes. The medicine can only be obtained with a prescription.

Ertapenem SUN is given at a dose of 1 g once a day in adults and adolescents. For younger patients (3 months to 12 years), a dose of 15 mg per kilogram body weight is given twice a day, up to a total of 1 g per day. Treatment with Ertapenem SUN lasts between 3 and 14 days, depending on the type and the severity of the infection. Once the infection has improved, treatment can be switched to an antibiotic that can be given by mouth.

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For preventing infection after colorectal surgery in adults, a single dose of Ertapenem SUN is given within 1 hour before the operation.

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

How does Ertapenem SUN work?

The active substance in Ertapenem SUN, ertapenem, belongs to the group of antibiotics known as 'carbapenems'. It attaches to certain proteins on the bacteria cells. This upsets the essential functions that keep these cells alive, and so kills the bacteria. Ertapenem SUN can work on a range of different bacteria.

How has Ertapenem SUN been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Invanz, and do not need to be repeated for Ertapenem SUN.

As for every medicine, the company provided studies on the quality of Ertapenem SUN. There was no need for 'bioequivalence' studies to investigate whether Ertapenem SUN is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Ertapenem SUN is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Ertapenem SUN?

Because Ertapenem SUN is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ertapenem SUN authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Ertapenem SUN has been shown to have comparable quality and to be bioequivalent to Invanz. Therefore, the Agency's view was that, as for Invanz, the benefits of Ertapenem SUN outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Ertapenem SUN

Ertapenem SUN received a marketing authorisation valid throughout the EU on 15 July 2022.

Further information on Ertapenem SUN can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ertapenem-sun

This overview was last updated in 07-2022.