



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Invanz

ertapenem

This is a summary of the European public assessment report (EPAR) for Invanz. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Invanz.

For practical information about using Invanz, patients should read the package leaflet or contact their doctor or pharmacist.

What is Invanz and what is it used for?

Invanz is an antibiotic. It is used in adults and children aged over 3 months to treat the following infections:

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

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

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

Invanz contains the active substance ertapenem.

How is Invanz used?

Invanz 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.



Invanz 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 Invanz 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.

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

How does Invanz work?

The active substance in Invanz, 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 the cells alive, and so kills the bacteria. Invanz can work on a range of different bacteria, which are listed in the summary of product characteristics (also part of the EPAR).

What benefits of Invanz have been shown in studies?

Treatment of infections

Invanz was compared with ceftriaxone (another antibiotic) for the treatment of adults with community-acquired pneumonia (866 patients) and urinary tract infections (592 patients), and with a combination of piperacillin and tazobactam for the treatment of abdominal infections (655 patients), gynaecological infections (412 patients), skin and soft tissue infections (infections of the skin and the tissues just beneath the skin, 540 patients); and foot infections in diabetes patients (576 patients). In studies in children, Invanz was compared with ceftriaxone (for community-acquired pneumonia, 389 children) and with ticarcillin/clavulanate (for intra-abdominal infections, 105 children). The studies examined if the infection was cured after 7 to 28 days of treatment, depending on the type of infection.

Invanz was as effective as ceftriaxone or piperacillin/tazobactam for the treatment of abdominal infections, community-acquired pneumonia, gynaecological infections and foot infections in diabetes patients: Invanz was effective for 87 to 94% of patients compared with 83 to 92% for the comparator antibiotics. However, the data were not sufficient to support the use of Invanz in the treatment of urinary tract infections and skin and soft tissue infections, except foot ulcers in diabetes patients. In children, Invanz was as effective as the comparator antibiotics and had similar effectiveness to that in adults.

Prevention of infections after colorectal surgery

Invanz was compared with cefotetan for preventing infection after colorectal surgery. Effectiveness was measured as absence of infection 4 weeks after treatment, which involved 952 adults. Infection was absent in about 60% patients given Invanz compared with 49% of patients given cefotetan.

What are the risks associated with Invanz?

The most common side effects with Invanz (which may affect up to 1 in 10 people) are headache, diarrhoea, nausea (feeling sick), vomiting, rash (including nappy rash in children), itching, and problems around the area where the medicine is infused (including pain and inflammation of the vein). Invanz also has an effect on some blood tests. For the full list of all side effects reported with Invanz, see the package leaflet.

Invanz must not be used in people who are hypersensitive (allergic) to ertapenem or to other antibiotics of the same group (carbapenems). It must also not be used in patients who are severely allergic to other types of antibiotics, such as penicillins and cephalosporins. For the full list of restrictions see the package leaflet.

Why is Invanz approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Invanz's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that Invanz was shown to be effective, albeit with a limited number of severe cases treated during the studies for abdominal infections, community-acquired pneumonia, gynaecological infections and diabetic foot infections. The Committee concluded that it was also effective for treatment of infection in children and for preventing infection after colorectal surgery in adults.

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

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

Other information about Invanz

The European Commission granted a marketing authorisation valid throughout the European Union for Invanz on 18 April 2002.

The full EPAR for Invanz can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Invanz, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.