

INVANZ™ (ertapenem sodium)

Fact Sheet

A structurally unique 1-b methyl-carbapenem belonging to the class of antibiotics known as beta-lactams (such as penicillins and cephalosporins), INVANZ™ (ertapenem sodium) is a sterile, synthetic antibiotic with in vitro activity against a range of gram-positive and gram-negative aerobic and anaerobic bacteria.

Indications

- Once daily ertapenem is indicated for the treatment of moderate to severe infections caused by many common bacteria that grow with or without oxygen and specifically for the initial and empiric monotherapy of patients with the following moderate to severe infections:
 - ✓ Complicated intra-abdominal infections;
 - ✓ Complicated skin and skin structure infections;
 - ✓ Community-acquired pneumonia;
 - ✓ Complicated urinary tract infections including pyelonephritis;
 - ✓ Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynaecologic infections.

Mode of action

- Like other beta-lactams, ertapenem works by blocking the formation of the bacterial cell wall, causing cell death.

Efficacious across all indications

- Clinical studies have found that the efficacy of ertapenem against complicated intra abdominal infections was similar to drugs dosed multiple times a day:
 - ◆ one-gram of ertapenem injected once daily was statistically equivalent to 3.375 grams of piperacillin/tazobactam given to patients every six hours.¹
 - ◆ ertapenem one-gram once daily, with the option to switch to an oral regimen after clinical improvement, appeared similar to the combined regimen of ceftriaxone two grams daily plus metronidazole 500 mg every eight hours, with the same oral switch option.²
- The pivotal Phase IIb/III trials demonstrated the results for clinical success rates with ertapenem compared to widely used antibiotics for patients treated for:
 - ◆ *Complicated intra-abdominal infections:* 86.7 per cent of patients on ertapenem were clinically and microbiologically cured at four to six weeks post-therapy compared with 81.3% for piperacillin/tazobactam;³
 - ◆ *Complicated skin and skin structure infections:* 82.2 per cent of patients on ertapenem were clinically cured 10 to 21 days post-therapy compared with 84.5 per cent for piperacillin/tazobactam;³
 - ◆ *Community-acquired pneumonia:* ertapenem was evaluated in two randomized, multicentred, double-blind controlled trials. Both studies compared one-gram once a day of ertapenem with ceftriaxone. The clinical success rates (of the combined studies) at seven to 14 days post therapy were 92 per cent for ertapenem and 91.8 per cent for ceftriaxone;³

- ◆ *Complicated urinary tract infections:* ertapenem was evaluated in two randomized, multicentred, double-blind controlled studies. 89.5 per cent of patients on ertapenem were microbiologically cured five to nine days post-therapy compared with 91.1 per cent for ceftriaxone in the combined studies;³
- ◆ *Acute pelvic infections:* 93.9 per cent of patients on ertapenem were clinically cured two to four weeks post-therapy compared with 91.5 per cent for piperacillin/tazobactam.³
- Ertapenem has limited activity against *Pseudomonas* and *Acinetobacter* species—pathogens typically associated with hospital-acquired infections. Enterococci and methicillin resistant staphylococci are resistant to ertapenem.

Proven tolerability

- In clinical studies with over 1,800 patients, the overall tolerability profile of ertapenem was similar to compared treatments.³
- Clinical studies have demonstrated that the tolerability profile of ertapenem in the elderly (≥ 65 years) was comparable to that seen in younger patients (≤ 65 years).³
- Across studies in five infectious disease categories, the most common clinical side effects were infused vein complications (3.9 per cent), phlebitis/thrombophlebitis (1.3 per cent), diarrhea (4.3 per cent), nausea (2.9 per cent), headache (2.1 per cent) and vomiting (1.0 per cent).

Dosage

- Ertapenem is given as a one-gram dose, once daily in monotherapy.
- Ertapenem can be administered either by intravenous infusion or intramuscular injection, providing treatment flexibility and convenience.

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References

1. Solomkin JS, Yellin AE et al. Ertapenem Versus Piperacillin/Tazobactam in the Treatment of Complicated Intraabdominal Infections: Results of a Double-Blind, Randomized Comparative Phase III Trial. *Annals of Surgery* 237(2): 235-245; Feb 2003
2. Yellin AE, Hassett JM et al. Ertapenem monotherapy versus combination therapy with ceftriaxone plus metronidazole for treatment of complicated intra-abdominal infections in adults. *International Journal of Antimicrobial Agents* 20 (2002) 165-173
3. INVANZ™ Canadian Product Monograph

- 30 -

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