נובמבר 2021

רופא/ה יקר/ה,
רוקח/ת יקר/ה,

הנדון: <u>אינבנז - INVANZ®</u>

Dosage form: Lyophillized Powder for Injection
Composition: Ertapenem (as sodium) 1 gr/vial

חברת מרק שארפ ודוהם (ישראל-1996) בע"מ, (MSD ישראל), מבקשת ליידע על עדכון העלון לרופא של התכשיר INVANZ.

להלן לשון ההתוויות המאושרות לתכשיר:
Invanz is indicated for the treatment of adult patients and pediatric patients (3 months of age and older) with the following moderate to severe infections caused by susceptible isolates of the designated microorganisms.
- Complicated intra-abdominal infections.
- Complicated skin and skin structure infections including diabetic foot infections without osteomyelitis.
- Community acquired pneumonia.
- Complicated urinary tract infections including pyelonephritis.
- Acute pelvic infections including postpartum endomyometritis septic abortion and post surgical gynecologic infections.

למידע מלא ולהוראות מתן מפורטות, יש לעיין בעלון לרופא המאושר על ידי משרד הבריאות.

<u>עדכונים מהותיים שבוצעו בעלון לרופא:</u>
מחיקת מידע הקשור להתוויה למניעה, שאינה רשומה בישראל, מסעיפים 1, 6.1 ו-6.3. טקסט שנמחק מופיע עם קו חוצה.

1 INDICATIONS AND USAGE

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1.6 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of INVANZ and other antibacterial drugs, INVANZ should be used only to treat ~~or prevent~~ infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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6 ADVERSE REACTIONS

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6.1 Clinical Trials Experience

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~~Prophylaxis of Surgical Site Infection following Elective Colorectal Surgery~~

~~In a clinical trial in adults for the prophylaxis of surgical site infection following elective colorectal surgery in which 476 patients received a 1 g dose of INVANZ 1 hour prior to surgery and were then followed for safety 14 days post surgery, the overall adverse experience profile was generally comparable to that observed for INVANZ in previous clinical trials. Table 4 shows the incidence of adverse experiences other than those previously described above for INVANZ that were reported regardless of causality in ≥2.0% of patients in this trial.~~

~~Table 4~~
~~Incidence (%) of Adverse Experiences Reported During Study Therapy Plus 14-Day Follow-Up in ≥2.0% of Adult Patients Treated With INVANZ for Prophylaxis of Surgical Site Infections Following Elective Colorectal Surgery~~

Adverse Events	INVANZ 1 g (N = 476)	Cefotetan 2 g (N = 476)
Anemia	5.7	6.9
Small intestinal obstruction	2.1	1.9
Pneumonia	2.1	4.0
Postoperative infection	2.3	4.0
Urinary tract infection	3.8	5.5
Wound infection	6.5	12.4
Wound complication	2.9	2.3
Atelectasis	3.4	1.9

Additional adverse experiences that were reported in this prophylaxis trial with INVANZ, regardless of causality, with an incidence >0.5% within each body system are listed below:

Gastrointestinal Disorders: *C. difficile* infection or colitis, dry mouth, hematochezia

General Disorders and Administration Site Condition: crepitations

Infections and Infestations: cellulitis, abdominal abscess, fungal rash, pelvic abscess

Injury, Poisoning and Procedural Complications: incision site complication, incision site hemorrhage, intestinal stoma complication, anastomotic leak, seroma, wound dehiscence, wound secretion

Musculoskeletal and Connective Tissue Disorders: muscle spasms

Nervous System Disorders: cerebrovascular accident

Renal and Urinary Disorders: dysuria, pollakiuria

Respiratory, Thoracic and Mediastinal Disorders: crackles lung, lung infiltration, pulmonary congestion, pulmonary embolism, wheezing.

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6.3 Adverse Laboratory Changes in Clinical Trials

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Prophylaxis of Surgical Site Infection following Elective Colorectal Surgery

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בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו. העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת MSD ישראל, בטלפון 09-9533333.
INVNAZ מופץ ע"י חברת נובולוג בע"מ.

בברכה,

מיכל סרפר
רוקחת ממונה
MSD ישראל

Refrences:
INVANZ SPC 11/2021