



פיזר פ' א' פרמצבטיקה ישראל בע"מ
רחוב שנקר 9, תל. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700501 פקס: 972-9-9700500

מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא עבור התכשירים הבאים:

Meronem 500 MG

Meronem 1G

המרכיב הפעיל:

Meropenem (as trihydrate)

התויה:

Meronem is indicated for treatment in adults and children of the following severe infections caused by single

or multiple susceptible bacteria sensitive to meropenem:

- Pneumonias and nosocomial pneumonias.
- Pulmonary infections in patients with cystic fibrosis.
- Urinary tract infections.
- Intra-abdominal infections.
- Gynecological infections such as endometritis and pelvic inflammatory disease.
- Skin and skin structure infections.
- Meningitis.
- Septicemia.

Meronem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

There is no experience in pediatric patients with neutropenia or primary or secondary immunodeficiency.

להלן העדכנים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

.....

Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and acute generalised exanthematous pustulosis (AGEP) have been reported in patients receiving meropenem (see section 4.8). If signs and symptoms suggestive of these reactions appear, meropenem should be withdrawn immediately and an alternative treatment should be considered.

Antibiotic-associated colitis

Antibiotic-associated colitis and pseudomembranous colitis have been reported with nearly all anti-bacterial agents, including meropenem, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of meropenem (see section 4.8). Discontinuation of therapy with meropenem and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

.....

4.8 Undesirable effects

.....

System Organ Class	Frequency	Event
Infections and infestations	Uncommon	oral and vaginal candidiasis
Blood and lymphatic system disorders	Common Uncommon	thrombocythaemia agranulocytosis, haemolytic anaemia, thrombocytopenia, neutropenia, leukopenia, eosinophilia
Immune system disorders	Uncommon	, anaphylaxis (see sections 4.3 and 4.4), angioedema
Psychiatric disorders	Rare	delirium
.....		
Skin and subcutaneous tissue disorders	Common Uncommon Not known	rash, pruritus toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme. (see section 4.4), urticaria drug reaction with eosinophilia and systemic symptoms, acute generalised exanthematous pustulosis (see section 4.4)
Renal and urinary disorders	Uncommon	blood creatinine increased, blood urea increased
General disorders and administration site conditions	Common Uncommon	inflammation, pain thrombophlebitis, pain at the injection site

.....

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים בעלון לרופא הכלולים תוספת מידע, השמטה מידע ועדכוני נוסח שאינם מהווים החמרה. בהודעה זו מצוינים רק העדכונים העיקריים. קיימים עדכונים נוספים.

העלון המעודכן נשלח לשירות הבריאות לצורכי פרסום במאגר התרופות שבמשרד הבריאות הבינאות:

<https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=1>

לחילופין, קיבלת עלון מלא מודפס ניתן לפנות לחברת פיזר פי אפי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
עשית אושריה
רוקחת ממונה