Vabomere

(meropenem, vaborbactam)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Vabomere
- **Generic name:** Meropenem, vaborbactam
- **Pharmacological class:** Carbapenem + beta-lactamase inhibitor
- **Strength and Formulation:** 2g/vial (containing meropenem 1g + vaborbactam 1g); pwd for IV infusion after reconstitution and dilution; sodium content 10.9mEq/vial; preservative-free
- **Manufacturer:** The Medicines Company
- **How supplied:** Single-dose vials—6
- **Legal Classification:** Rx

Vabomere


Rx only
NDC 65293-009-06
VABOMERE™
(meropenem and vaborbactam)
for injection
2 g per vial*
*Meropenem 1 gram (equivalent to 1.14 g meropenem trihydrate) and vaborbactam 1 g
For Intravenous Infusion Only
Single Dose Only
Discard Unused Portion After Use
MUST BE CONSTITUTED THEN DILUTED
See prescribing information for constitution and dilution instructions and complete directions for use.
Storage:
Store at 20°C to 25°C (68°F to 77°F); excursions are permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]
Manufactured by:
Facta Farmaceutici S.p.A.
Nucleo Industriale S. Atto
S. Nicolò a Tordino
64100 Teramo (TE) Italy
Marketed by:
The Medicines Company
Parsippany, NJ 07054
Product of Italy
Contains 6 single dose 2 g vials
PN 1502
VABOMERE

Indications

- Susceptible **complicated urinary tract infections** (cUTI) including pyelonephritis

Dosage & Administration

- Give by IV infusion over 3hrs
- **≥18yrs** (eGFR ≥50mL/min/1.73m^2): 4g every 8hrs
- Renal impairment
  - eGFR 30–49mL/min/1.73m^2: 2g every 8hrs
  - eGFR 15–29mL/min/1.73m^2: 2g every 12hrs
  - eGFR <15mL/min/1.73m^2: 1g every 12hrs
- Give after hemodialysis session
- All: treat for up to 14 days

Considerations for Special Populations

- **Pediatric:** <18yrs: not established
- **Pregnancy:** Insufficient human data to establish drug-associated risk
- **Nursing mothers:** Consider mother's need and potential adverse effects on child
- **Elderly:** Monitor renal function
- **Renal impairment:** See Dosage & Administration

Warnings/Precautions

- Previous **hypersensitivity** to penicillins, cephalosporins, other beta-lactams, or other allergens
- **Discontinue immediately** if allergic reaction occurs
- CNS disorders (eg, brain lesions, history of seizures)

Warnings/Precautions

- Bacterial meningitis
- Renal impairment (thrombocytopenia possible)
- Reevaluate dose if focal tremors, myoclonus, or seizures occur
- Discontinue if *C. difficile*-associated diarrhea suspected or confirmed

Interactions

- Concomitant **valproic acid** or **divalproex sodium**: not recommended; if use necessary, consider supplemental anticonvulsant
- Potentiated by **probenecid**: not recommended

Adverse Reactions

- Headache
- Phlebitis/infusion site reactions
- Diarrhea
- Serious hypersensitivity reactions
- *C. difficile*-associated diarrhea
- Possible neuromotor impairment
- Superinfection

Mechanism of Action

- **Meropenem** penetrates the cell wall of most gram-positive and gram-negative bacteria to bind penicillin-binding protein (PBP) targets
- **Vaborbactam** is a non-suicidal beta-lactamase inhibitor that protects meropenem from degradation by certain serine beta-lactamases such as *Klebsiella pneumoniae* carbapenemase
  - It does not have any antibacterial activity

Clinical Studies

- Vabomere was compared to piperacilln/tazobactam IV every 8hrs in a randomized, double-blind, double dummy, multicenter trial (n=545) in adults with cUTI, including pyelonephritis

Clinical Studies

- Clinical and microbiological response at the end of IV treatment (EOIVT) required both a clinical outcome of cure or improvement and a microbiologic outcome of eradication
- This was also assessed at the Test of Cure (TOC) visit ~7 days after treatment completion
  - Mean duration of IV treatment was 8 days in both treatment groups; mean total treatment duration (IV and oral) was 10 days

Clinical Studies

- Vabomere showed efficacy with regard to clinical and microbiological response at the EOIVT visit and TOC visits in the microbiologically modified intent-to-treat population (m-MITT)
  - EOIVT: **98.4%** Vabomere vs. **94.3%** pip/tazo
  - TOC: **76.5%** Vabomere vs. **73.2%** pip/tazo

Clinical Studies

- In the m-MITT population, the rate of clinical and microbiological response in Vabomere-treated patients with concurrent bacteremia at baseline was 10/12 (**83.3%)**

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/vabomere/drug/34753/