Antiparasitic Drugs, Hard-to-Find, Sources

Antiparasitic Drugs, Sources

- Listings below are not comprehensive.

- Many of the drugs recommended for antiparasitic therapy are either not licensed or not readily available (either in the U.S. or elsewhere).

- Tafenoquine FDA approved in 2018. US availability in retail pharmacies is variable.

- Moxidectin FDA approved in 2018 but currently no commercialization or availability plans for the U.S.

- Quinacrine no longer available at any compounding pharmacy in the US; Quinacrine HCl may be used to compound oral drug products under section 503B of the FD&C; Act, compounded drugs such as quinacrine HCl are not reviewed and approved by FDA for safety, effectiveness, or quality

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- Drugs discontinued by CDC Drug Service in recent years due to commercial availability, non-CDC IND, or complete discontinuation. IV artesunate Sodium stibogluconate (Pentostam) Discontinued by manufacturer (GSK); use Glucantime via Sanofi IND (see below) Nifurtimox Benznidazole Triclabendazole

- IV artesunate

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- Benznidazole

- Triclabendazole

CDC Malaria Branch

- CDC Malaria Hotline (770-488-7788) from 9:00 am to 5:00 pm Eastern Time. After hours or on weekends and holidays, call the CDC Emergency Operation Center at 770-488-7100 and ask to page the person on call for the Malaria Branch.

- No longer provides any antimalarial drugs.

CDC Drug Service

- CDC Parasitic Diseases Inquiries (404-718-4745; email parasites@cdc.gov) M-F 7:30am-4pm ET OR

- CDC Drug Service or call (+1) 404-639-3670; drugservice@cdc.gov

- Contact for the availability of these drugs:

- Diethylcarbamazine (DEC); Manufactured by E.I.P.I.C.O.

- Eflornithine (DFMO); Manufactured by Sanofi Aventis – Ornidyl®

- Melarsoprol; Manufactured by Sanofi Aventis – Arsobal®

- Suramin; Manufactured by Bayer – Germanin

WHO

- Drugs for treatment of African trypanosomiasis

- Dr Gerardo Priotto priottog@who.int

- Dr. Jose Ramon Franco: francoj@who.int; (+41) 796-198-535; (+41) 227-913-313

- Stocks of these drugs placed at several international locations; see J Travel Med 19:44, 2012 Fexinidazole available as a donation from Sanofi to national government programs

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Specialty Distributors, Pharmacies, Labs

- FDA approved Artesunate for Injection (intravenous artesunate; Amivas), is now commercially available in the US through major distributors (Cardinal Health, Americsource Bergen, and McKesson). See https://ivartesunate.com for distributors' 24/7 emergency numbers; If access problems from distributors, all voice messages directly to Amivas will receive a response in <30 minutes. Wholesale cost is $5,000 USD per vial; the average 80 kg person requires 6 vials for the first day and then 2 vials per day for each subsequent day that parasitemia is greater than 1%. CDC no longer distributes no-cost antimalarial drugs.

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Vancomycin AUC Dosing Fundamentals and Calculations

Introduction

- Area under the serum concentration vs. time curve for 0-24 hours (AUC24) has emerged as the preferred method for monitoring vancomycin therapy in patients with serious MRSA bacteremia, endocarditis, and invasive infection.

- See Am J Health Sys Pharm 2020, 77:835. The target AUC24 is 400-600 µg/mL x hr regardless of MIC. Note: traditional pediatric dosing of 45-60 mg/kg/day frequently does not achieve target AUC in term infants and older children with normal renal function. Use of AUC24 closer to 400 µg/mL is adequate for most non-CNS infections. Clin Infect Dis Jul 13 2020 Comprehensive "pro" and "con" discussion: Clin Infect Dis 2021; 72:1497 & 1502

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- Comprehensive "pro" and "con" discussion: Clin Infect Dis 2021; 72:1497 & 1502

- The Sanford Guide Vancomycin AUC calculator uses two postdistributional concentrations obtained at steady state to determine AUC24 with log-linear equations. The AUC for one dosage interval is

separated into two trapezoids, AUC under the infusion curve (AUCinf) and AUC under the elimination curve (AUCelim). The sum of AUCinf and AUCelim provides AUC for one dosage interval, and AUC24 is subsequently calculated.

- The measured peak and trough concentrations are back-extrapolated and forward-extrapolated to the true peak and true trough, respectively, to capture as much of the AUC for one dosage interval as possible.

- Calculating AUC24 in this manner inevitably slightly underestimates the true AUC24 because of a small area not captured by the two trapezoids.

AUC Dosing Calculator

- Vancomycin AUC dosing calculator

Calculator Assumptions

- Vancomycin peak and trough concentration, obtained under steady-state conditions. Steady-state requires 4-5 elimination half-lives. Here is the approximate half-life of vancomycin as a function of CrCl:

Pediatric Use

- None of the equations used are age-specific, and no age-specific assumptions are made during any calculation. Doses are entered (not selected), so they are not constrained by the size of doses typically used in adults. Therefore the calculation is based on kinetics from the measured levels and not PK parameters that change with age. For these reasons, the AUC calculator may be used for both adults and children.

Data Required by the Calculator

- Vancomycin dose (mg)

- Dosing interval (Tau, in hours)

- Duration of Vancomycin infusion (Tinf, in hours)

- Measured Vancomycin peak concentration (µg/mL)

- Time from start of Vancomycin infusion to measurement of peak concentration (T1, in hours)

- Measured Vancomycin trough concentration (µg/mL)

- Time from start of Vancomycin infusion to measurement of trough concentration (T2, in hours)

Example of Data Entry

- A patient with normal renal function is receiving vancomycin 1 gm IV q12h. A trough is drawn 30 minutes before the fourth dose, the fourth dose is infused over one hour, and the peak is drawn one hour after the infusion is complete. Because the patient is at steady state, the trough concentration measured 30 minutes before the fourth dose will be equivalent to a trough measured 30 minutes before the fifth dose (refer to above graphic). The peak is reported as 22 µg/mL, trough 8 µg/mL. These data are entered into the calculator: Dose (mg): 1000 Dosing interval (Tau, hours): 12 Duration of infusion (Tinf, hours): 1 Measured peak (µg/mL): 22 Time from start of infusion to peak (T1, hours): 2 Measured trough (µg/mL): 8 Time from start of infusion to trough (T2, hours): 11.5

- Dose (mg): 1000

- Dosing interval (Tau, hours): 12

- Duration of infusion (Tinf, hours): 1

- Measured peak (µg/mL): 22

- Time from start of infusion to peak (T1, hours): 2

- Measured trough (µg/mL): 8

- Time from start of infusion to trough (T2, hours): 11.5

- The calculator determines the AUC24 to be 349 µg/mL x hr (outside the target range). It also reports the daily dose range that will achieve the target AUC24 of 400-600 µg/mL x hr. The user can then input a new combination of dose, duration of infusion, and dosing interval, and the calculator predicts the AUC24, peak, and trough concentration that should result.

Equations: Calculation of AUC24

- Subsequent dose adjustments can be determined using the calculated AUC24 because the AUC24 is proportional to total daily dose.

- If the calculated AUC24 falls outside the target range, dose or interval (or both) can be adjusted to achieve a value in the range. If the AUC24 is already within the range, dose can be adjusted to target the upper or lower end of the range as desired, e.g., to achieve an AUC24 close to 400 for pediatric dosing.

Dose Adjustment

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Equations: Predicted Peak and Trough

Continuous, Prolonged Infusion Dosing

Continuous or Prolonged Dosing

- The best predictor of bacterial killing by beta-lactam antibiotics (Penicillins, Cephalosporins, Monobactams (Aztreonam), and Carbapenems) is the time during the dosage interval that the free (non-protein bound) drug concentration exceeds the MIC of the target organism(s) (Nat Rev Microbiol 2:289, 2004). It is possible to determine the probability that a given dosing regimen will achieve the desired drug exposure across a range of organism MICs using a variety of models (Antimicrob Agents Chemother 48:4718, 2004).

- There is gradual implementation of this approach for clinical use.

- Implementation of either a prolongation of infusion of each dose or continuous infusion over 24 hrs is, in available publications, efficacious and cost saving. Expense is reduced both by a reduction in the amount of drug needed per day plus less labor expense with simplified regimens.

- Antibiotic stability is a concern. Factors influencing stability include drug concentration, IV infusion diluent (e.g. NS vs. D5W), type of infusion device, and storage temperature (Pharm & Therap 36:723, 2011). Portable pumps worn close to the body expose antibiotics to temperatures closer to body

temperature (37ºC) than room temperature (around 25ºC). Carbapenems are particularly unstable and may require wrapping of infusion pumps in cold packs or frequent changes of infusion bags or cartridges.

- Based on current and rapidly changing data, it appears that prolonged or continuous infusion of beta-lactams is at least as successful as intermittent dosing. Hence, this approach can be part of stewardship programs as supported by recent publications.

- A meta-analysis of observational studies found reduced mortality among patients treated with extended or continuous infusion of Carbapenems or Piperacillin-Tazobactam (pooled data) as compared to standard intermittent therapy regimens. The results were similar for extended and continuous regimens when considered separately. There was a mortality benefit with Piperacillin-Tazobactam but not with Carbapenems (Clin Infect Dis 56:272, 2013). The lower mortality could, at least in part, be due to closer professional supervision engendered by a study environment. On the other hand, a small prospective randomized controlled study of continuous vs. intermittent Piperacillin-Tazobactam and Meropenem found a higher clinical cure rate and a trend toward lower mortality in the continuous infusion patients (Clin Infect Dis 56:236, 2013). An individual patient data meta-analysis of a large critical care population with severe sepsis found decreased mortality and increased clinical cure rate with beta-lactams administered by continuous infusion vs. intermittent dosing (Am J Respir Crit Care Med 194:681, 2016). In a recent secondary analysis of a prospective multicenter study of cirrhotic patients with bloodstream infection, the administration of continuous/extended infusion of Piperacillin-Tazobactam or Carbapenems vs intermittent infusion was associated with improved survival (Clin Infect Dis 2019;69:1731).

- This Table summarizes the current state of the art for either prolonged infusion or continuous infusion of those beta-lactams for which a reasonable database exists. Some fine points are in flux. Some investigators have elected to start with an initial (“loading”) dose and some have not. Further, the interval between an “initial” dose and the first prolonged infusion or the start of the continuous infusion is, at this time, an educated guess.

Specific Drug Regimens

- Minimum stability at 37ºC (body temperature), 25ºC (room temperature), and 4ºC (approximate cold pack temperature) is listed for each drug. ND=no data.

Dosing Abbreviations

ECMO Drug Dosing Adjustment

Introduction

- Extracorporeal membrane oxygenation (ECMO) in critically ill patients can alter the pharmacokinetics and pharmacodynamics of drugs, including antibiotics. Our understanding of these alterations is evolving.

- Circuit Sequestration (CS) of a drug may significantly alter a patient's dosing requirements. The type of tubing, the oxygenator and pump, and the composition of priming solution all influence the degree of CS. CS is more likely with lipophilic and/or highly protein bound drugs.

- The type of tubing, the oxygenator and pump, and the composition of priming solution all influence the degree of CS.

- CS is more likely with lipophilic and/or highly protein bound drugs.

- Increased volume of distribution (Vd) is typically observed with hydrophilic drugs (hemodilution). CS also increases the Vd.

- Altered drug clearance (CL) may also be observed. Increased clearance results from increased cardiac output, fluid resuscitation, and inotropic support, whereas decreased clearance results from renal dysfunction (many ECMO patients require renal replacement therapy).

- Narrative review of the impact of ECMO on drug PK/PD: Ann Pharmacother 2023;57:706.

- Review of antifungal drug dosing in critically ill patients on ECMO: Clin Pharmacokinet 2023 June 10 [online ahead of print].

Dosing adjustments in ECMO

- Suggested dosing relative to critically ill patients not on ECMO support

- CS=circuit sequestration, Vd = volume of distribution, CL = drug clearance, TDM = therapeutic drug monitoring, Cmax = maximum serum concentration, Cmin = minimum serum concentration

Hepatic Impairment, Dosing Adjustment

Introduction

- The following alphabetical list indicates antimicrobial drug excreted or metabolized by the liver for which a dosage adjustment may be indicated in the presence of hepatic disease. Consult the drug page for details. List is not all-inclusive.

- Most recommendations are from manufacturer's prescribing information.

- Reference for antiretroviral agents: Clin Infect Dis 2005;40:174.

Antibacterials / Antimycobacterials

- Ceftriaxone

- Chloramphenicol

- Clindamycin

- Eravacycline

- Fusidic acid

- Isoniazid

- Lefamulin IV (avoid tablets in moderate-to-severe hepatic impairment)

- Metronidazole

- Nafcillin

- Quinupristin-dalfopristin

- Rifabutin

- Rifampin

- Telithromycin (if patient also has CrCl <30 mL/min)

- Tigecycline

- Tinidazole

Antifungals

- Caspofungin
- Isavuconazonium sulfate
- Itraconazole
- Voriconazole

Antiparasitics

- Benznidazole
- Nifurtimox
- Praziquantel

Antiretrovirals

- Abacavir
- Atazanavir
- Darunavir
- Efavirenz
- Fosamprenavir
- Indinavir
- Lopinavir-ritonavir
- Nelfinavir
- Ritonavir

Antivirals

- Rimantadine
- Tofacitinib

Inhalation Dosing & Therapy

Introduction

- There is interest in inhaled antimicrobials for several patient populations, such as those with bronchiectasis due to cystic fibrosis or as a result of other conditions. Interest is heightened by growing incidence of infection, especially pneumonia, due to multidrug-resistant gram-negative bacilli. Isolates of Pseudomonas aeruginosa, Acinetobacter baumannii, or Klebsiella species susceptible only to Colistin are of special concern.

- There are a variety of ways to generate aerosols for inhalation: inhalation of dry powder, jet nebulizers, ultrasonic nebulizers, and most recently, vibrating mesh nebulizers. Current opinion favors vibrating mesh inhalers that generate fine particle aerosols with enhanced delivery of drug to small airways (Cochrane Database Syst Rev 4:CD007639, 2013).

- The 2016 IDSA Guideline on ventilator-associated pneumonia (VAP) suggests augmenting parenteral therapy with inhaled antibiotics, especially for highly resistant bacteria: Clin Infect Dis 2016; 63:575.

Adverse Events

- Airway irritation that may lead to bronchospasm. Pretreatment with albuterol may prevent.

- Expiratory filters may become occluded.

Indications & Dosing

- Cystic fibrosis Inhaled antibiotics are approved by the US FDA and by the European Medicines Agency for cystic fibrosis caused by P. aeruginosa in persons age > 6 or 7 years Aztreonam (FDA approved) Tobramycin inhalation solution (FDA approved) Tobramycin inhalation powder (FDA approved) Colistimethate dry powder (EMA approved)

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- Aztreonam (FDA approved)

- Tobramycin inhalation solution (FDA approved)

- Tobramycin inhalation powder (FDA approved)

- Colistimethate dry powder (EMA approved)

- Mycobacterium avium complex (MAC) Liposomal Amikacin for refractory disease

- Liposomal Amikacin for refractory disease

Cystic Fibrosis

- Aztreonam (Cayston)

Mycobacterium Avium Complex (MAC)

- Liposomal Amikacin (Arikayce)

Intraperitoneal Drug Dosing, CAPD

Clinical Setting

- See Treatment of CAPD peritonitis in adults for complete discussion.

- ISPD 2022 treatment guidelines: Perit Dial Int 2022;42:110.

- General review: New Engl J Med 2021; 385: 1786

- For antiretroviral drugs, see Kidney International 60:821, 2001.

Empiric Therapy

- Initiate antibiotics ASAP after collection of peritoneal fluid & blood for culture.

- Can treat by IP route or systemic IV therapy, but guidelines favor IP therapy.

- No single regimen has been proven to be superior to others.

- Empiric regimens should cover both gram-positive and gram-negative organisms, and be guided by local susceptibilities. Recommended: (Vancomycin or Cefazolin) + (3rd-generation Cephalosporin or

Aminoglycoside). Cefepime monotherapy may be an acceptable alternative.

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- Treatment failure with 3rd-generation cephalosporins, e.g., ceftazidime, is more likely with ESBL-producing organisms.

- Fluoroquinolone monotherapy is not recommended.

- Prolonged courses of IP aminoglycoside should be avoided. Adjunctive N-acetylcysteine (600 mg po q12h) may help to prevent ototoxicity.

- Optimal antibiotic dosing in patients with significant residual renal function is unknown. Fixed dosing regimens regardless of residual function might be particularly problematic for antibiotics that exhibit time-dependent killing (e.g., cephalosporins).

Intraperitoneal (IP) Therapy

- Can be either continuous (drugs in each exchange) or intermittent (once daily).

- If intermittent, need antibiotic-containing dialysis fluid to dwell for minimum 6 hours.

- Compatible in the same PD bag: Gentamicin + (Cefazolin or Vancomycin). Ceftazidime + (Cefazolin or Vancomycin).

- Gentamicin + (Cefazolin or Vancomycin).

- Ceftazidime + (Cefazolin or Vancomycin).

- Penicillins and aminoglycosides cannot be combined in the same PD bag.

- Most studies of IP antibiotics have been conducted in patients on CAPD rather than automated peritoneal dialysis (APD). Extrapolation of antibiotic dosing from CAPD to APD is not recommended.

Specific Dosing Recommendations

Obesity Dosing Adjustments

Introduction

- The number of obese patients is increasing. Intuitively, the standard doses of some drugs may not achieve effective serum concentrations. Pertinent data on anti-infective dosing in the obese patient are gradually emerging. Even though some of the data need further validation, the following table reflects what is currently known.

- Obesity is defined as weight ≥ 20% over ideal body weight (Ideal BW) or body mass index (BMI) >30.

- Click for calculator: Ideal body weight (Ideal BW); body mass index (BMI); lean body weight (LBW)

- The pharmacokinetics of antibacterials in obese patients is emerging, but only some drugs have been evaluated. Those drugs for which data justifies a dose adjustment are summarized under Obesity Dosing Adjustment (table below).

No Dosing Adjustment

- Data indicate that no dosage adjustment is needed in obese patients for these drugs (Pharmacotherapy 37:1415, 2017): Ceftaroline Ceftazidime-avibactam Ceftolozane-tazobactam

Doripenem Imipenem-cilastatin Meropenem Oritavancin Tedizolid

- Ceftaroline

- Ceftazidime-avibactam

- Ceftolozane-tazobactam

- Doripenem

- Imipenem-cilastatin

- Meropenem

- Oritavancin

- Tedizolid

Obesity Dosing Adjustment

- Click drug for full information.

- Dose = suggested body weight (Actual, Ideal, or Adjusted body weight) for dose calculation in an obese patient, or specific dose if applicable.

Outpatient Parenteral Antimicrobial Therapy (OPAT)

Introduction

- Outpatient Parenteral Antimicrobial Therapy (OPAT) is the administration of parenteral antimicrobial therapy in ≥2 doses on different days without intervening hospitalization.

- In general, three models of OPAT delivery exist: home based, infusion center based, and skilled nursing facility based.

- Selection of infusion device depends on drug stability, dosing regimen, cost, and patient preference.

- Factors influencing stability include final drug concentration, diluent, temperature, pH, and type of infusion device.

- Methods of drug delivery (Open Forum Infect Dis 2022;9:ofac525) IV push Rapid, convenient Requires manual dexterity Programmable ambulatory pump Also known as continuous ambulatory delivery device (CADD) Allows for intermittent, continuous, and tapered infusions Elastomeric pump (the "infusion ball") Simple single-dose delivery system No batteries, gravity not required for flow Available in a variety of sizes (50 mL to 500 mL) and flow rates ranging from 5 mL/hr to 250 mL/hr Medication stability can vary between different devices Gravity infusion Infusion controlled by roller clamp, not pump Inexpensive Can be complex for patients to learn Stationary infusion pump Heavy, cumbersome Appropriate for certain care centers

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- Simple single-dose delivery system

- No batteries, gravity not required for flow

- Available in a variety of sizes (50 mL to 500 mL) and flow rates ranging from 5 mL/hr to 250 mL/hr

- Medication stability can vary between different devices

- Gravity infusion Infusion controlled by roller clamp, not pump Inexpensive Can be complex for patients to learn

- Infusion controlled by roller clamp, not pump

- Inexpensive

- Can be complex for patients to learn

- Stationary infusion pump Heavy, cumbersome Appropriate for certain care centers

- Heavy, cumbersome

- Appropriate for certain care centers

- IDSA guidelines: Clin Infect Dis 68:e1, 2019.

Dosing Table

- 1x/wk=weekly; 2x/wk=twice weekly

- BMP=basic metabolic panel (includes K+, BUN, SCr)

- LFTs=AST, ALT, alkaline phosphatase, total bilirubin

- IVP=IV push

- EP=elastomeric pump

Pediatric Dosing

Renal Impairment Dosing

Renal Impairment, No Dosing Adjustment

Introduction

- The following antimicrobial agents do not require dosage adjustment in patients with renal impairment.

- See drug for further details on the drug page.

- Most data are from the manufacturer's prescribing information.

Antibacterials

- Azithromycin

- Ceftriaxone

- Chloramphenicol

- Clindamycin
- Dicloxacillin
- Doxycycline
- Eravacycline
- Erythromycin
- Fidaxomicin
- Fusidic acid
- Lefamulin
- Linezolid
- Minocycline
- Moxifloxacin
- Nafcillin
- Omadacycline
- Oritavancin
- Pivmecillinam
- Polymyxin B
- Rifamycin SV
- Rifaximin
- Secnidazole
- Tedizolid
- Tigecycline

Antifungals

- Amphotericin B
- Anidulafungin
- Caspofungin
- Ibrexafungerp
- Isavuconazonium sulfate (note: SLED may reduce concentrations)
- Itraconazole (oral solution)
- Ketoconazole
- Micafungin (consider dose increase in CRRT)
- Posaconazole
- Voriconazole

Antimycobacterials

- Bedaquiline (use caution in severe impairment or ESRD)

- Isoniazid
- Rifampin
- Rifapentine

Antiparasitics

- Albendazole
- Artesunate
- Fexinidazole
- Mefloquine
- Paromomycin
- Praziquantel

Antiretrovirals / Antivirals

- Coronavirus. SARS CoV-2 Bamlanivimab-Etesevimab Bebtelovimab Casirivimab-Imdevimab Molnupiravir Remdesivir Sotrovimab
- Bamlanivimab-Etesevimab
- Bebtelovimab
- Casirivimab-Imdevimab
- Molnupiravir
- Remdesivir
- Sotrovimab
- HCV Daclatasvir Epclusa Harvoni Interferon alfa 2a, 2b Mavyret Sofosbuvir Vosevi Zepatier
- Daclatasvir
- Epclusa
- Harvoni
- Interferon alfa 2a, 2b
- Mavyret
- Sofosbuvir
- Vosevi
- Zepatier
- HIV Abacavir Atazanavir Cobicistat Darunavir Dolutegravir Efavirenz Enfuvirtide Etravirine Fosamprenavir Fostemsavir Ibalizumab-uiyk Indinavir Lopinavir-ritonavir Nelfinavir Nevirapine Raltegravir Rilpivirine (use with caution if CrCl <30 mL/min) Ritonavir Saquinavir Tipranavir
- Abacavir
- Atazanavir
- Cobicistat
- Darunavir

- Dolutegravir
- Efavirenz
- Enfuvirtide
- Etravirine
- Fosamprenavir
- Fostemsavir
- Ibalizumab-uiyk
- Indinavir
- Lopinavir-ritonavir
- Nelfinavir
- Nevirapine
- Raltegravir
- Rilpivirine (use with caution if CrCl <30 mL/min)
- Ritonavir
- Saquinavir
- Tipranavir
- Poxviruses Brincidofovir Tecovirimat
- Brincidofovir
- Tecovirimat

Sodium Content: Injectable Antimicrobials

Introduction

- The amount of sodium contained in intravenous antimicrobial agents may be of significance in sodium-restricted patients.

- Conversion: 1 mEq of sodium = 23 mg.

Sodium Content

- Sodium quantities below do not include the vehicle of administration, unless otherwise indicated.

- If the drug is administered in a normal saline (NS) vehicle, note that there are 7.7 mEq (177 mg) of sodium in a 50 mL infusion bag of NS, and 15.4 mEq (354 mg) in a 100 mL bag of NS.

- References: Manufacturer's prescribing information, Open Forum Infect Dis 2019;6:ofz508.