165.00 mm

420.00 mm

FPO

BEDAPT 500mg

(Daptomycin for Injection 500mg per vial)

PRODUCT DESCRIPTION

BEDAPT 500mg (Daptomycin for Injection 500mg per vial) is a pale yellow to light brown lyophilised cake or powder, packed in clear Type-I 10R/20mm tubular glass vial, stoppered with 20mm lyophilisation Type-I grey rubber bromobutyl closure and sealed with 20mm flip top aluminium seal. After reconstitution, it appears as a clear, pale yellow to light brown solution free from visible particles. Each vial contains Daptomycin 500mg.

PHARMACODYNAMICS

Mechanism of Action

The mechanism of action of daptomycin is distinct from that of any other antibacterial. Daptomycin binds to bacterial cell membranes and causes a rapid depolarization of membrane potential. This loss of membrane potential causes inhibition of DNA, RNA, and protein synthesis, which results in bacterial cell death.

Mechanism of Resistance

The mechanism(s) of daptomycin resistance is not fully understood. There are no known transferable elements that confer resistance to daptomycin. There is no cross-resistance due to resistance mechanisms that are specific for another class of antibacterials.

PK/PD Relationship

Daptomycin exhibits rapid, concentration-dependent bactericidal activity against Gram-positive bacteria.

Interactions with Other Antibacterials

There is no known antagonism in daptomycin interaction with other antibacterials. There may be synergistic interactions of daptomycin with aminoglycosides, β-lactam antibacterials, and rifampin against some isolates of staphylococci (including some methicillin-resistant isolates) and enterococci (including some vancomycin-resistant isolates).

PHARMACOKINETICS

General Characteristics

Daptomycin pharmacokinetics appears generally linear (dose-proportional) and time-independent at Daptomycin doses of 4 to 12 mg/kg administered by IV infusion over a 30-minute period as a single daily dose for up to 14 days in adults. Steady-state concentrations are achieved by the third daily dose.

Distribution

Daptomycin is reversibly bound to human plasma proteins. The protein binding of daptomycin in adult with mild to moderate hepatic impairment (Child-Pugh Class B) appears similar to that in healthy adult.

The volume of distribution at steady-state of daptomycin in healthy adult appears independent of dose. Daptomycin appears to penetrate the blood-brain barrier and the placental barrier only minimally following single and multiple doses.

Metabolism

It is unlikely that daptomycin will inhibit or induce the metabolism of drugs metabolized by the P450 system.

Inactive metabolites are detected in urine, by determining the difference between total radioactive concentrations and microbiologically active concentrations. The site of metabolism has not been identified.

Elimination

Daptomycin is excreted primarily by the kidneys. There is minimal to no active tubular secretion of daptomycin. About 6% of the administered dose is excreted in the feces. Plasma clearance of daptomycin is approximately 7 to 9 mL/h/kg, and its renal clearance is 4 to 7 mL/h/kg.

INDICATION

Daptomycin is indicated for the treatment of the infections listed below.

Complicated Skin and Skin Structure Infections

Adult (≥ 18 years of age) and pediatric (1 to 17 years of age) patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

***Staphylococcus aureus* Bloodstream Infections (Bacteremia)**

Adult patients (≥ 18 years of age) with *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.

Pediatric patients (1 to 17 years of age) with *S. aureus* bloodstream infections (bacteremia) caused by methicillin-susceptible and methicillin-resistant isolates.

Limitations of Use

Daptomycin is not indicated for the treatment of pneumonia.

Daptomycin is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*. Daptomycin has not been studied in patients with prosthetic valve endocarditis.

Usage

Appropriate specimens for microbiological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to daptomycin.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Daptomycin and other antibacterial drugs, Daptomycin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

When culture and susceptibility information is available, it 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. Empiric therapy may be initiated while awaiting test results.

DOSAGE FORM

Lyophilised powder for concentrate for solution for infusion.

ROUTE OF ADMINISTRATION

By intravenous infusion

RECOMMENDED DOSE

Administration

Daptomycin for Injection should be administered intravenously.

Adults

Complicated Skin and Skin Structure Infections

Daptomycin 4 mg/kg should be administered to adult patients intravenously in 0.9% sodium chloride injection once every 24 hours for 7 to 14 days by infusion over a 30-minute period.

***Staphylococcus aureus* Bloodstream Infections (Bacteremia)**

Daptomycin 6 mg/kg should be administered to adult patients intravenously in 0.9% sodium chloride injection once every 24 hours for 2 to 6 weeks by infusion over a 30-minute period. There are limited safety data for the use of Daptomycin for more than 28 days of therapy.

Pediatric Patients (1 to 17 Years of Age)

Complicated Skin and Skin Structure Infections

The recommended dosage regimens based on age for pediatric patients with cSSSI are shown in Table 1. Daptomycin should be administered intravenously in 0.9% sodium chloride injection once every 24 hours for up to 14 days.

Table 1: Recommended Dosage of Daptomycin in Pediatric Patients (1 to 17 Years of Age) with Complicated Skin and Skin Structure Infections, Based on Age

Age group	Dosage*	Duration of therapy
12 to17 years	5 mg/kg once every 24 hours infused over 30 minutes	Up to 14 days
7 to 11 years	7 mg/kg once every 24 hours infused over 30 minutes	
2 to 6 years	9 mg/kg once every 24 hours infused over 60 minutes	
1 to < 2 years	10 mg/kg once every 24 hours infused over 60 minutes	

*Recommended dosage is for pediatric patients (1 to 17 years of age) with normal renal function. Dosage adjustment for pediatric patients with renal impairment has not been established.

***Staphylococcus aureus* Bloodstream Infections (Bacteremia)**

The recommended dosage regimens based on age for pediatric patients with *S. aureus* bloodstream infections (bacteremia) are shown in Table 2. Daptomycin should be administered intravenously in 0.9% sodium chloride injection once every 24 hours for up to 42 days.

Table 2: Recommended Dosage of Daptomycin in Pediatric Patients (1 to 17 Years of Age) with *S. aureus* Bloodstream Infections, Based on Age

Age group	Dosage*	Duration of therapy
12 to 17 years	7 mg/kg once every 24 hours infused over 30 minutes	Up to 42 days
7 to 11 years	9 mg/kg once every 24 hours infused over 30 minutes	
1 to 6 years	12 mg/kg once every 24 hours infused over 60 minutes	

*Recommended dosage is for pediatric patients (1 to 17 years of age) with normal renal function. Dosage adjustment for pediatric patients with renal impairment has not been established.

(1) Minimum duration for pediatric bacteremia should be in accordance with the perceived risk of complications in the individual patient

Patients with Renal Impairment

The recommended dosage regimen for adult patients with creatinine clearance (CL_{cr}) <30 mL/min, including those on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD), is 4 mg/kg (cSSSI) or 6 mg/kg (*S. aureus* bloodstream infections) once every 48 hours (Table 3). When possible, Daptomycin should be administered following the completion of hemodialysis on hemodialysis days (see *Warnings and Precautions and Use in Specific Populations*).

The dosage regimen for Daptomycin pediatric patients with renal impairment has not been established.

Table 3. Recommended Dosage of Daptomycin in Adult Patients

Creatinine Clearance (CL_{cr})	Dosage Regimen	
	cSSSI	*S. aureus* Bloodstream Infections
≥30 mL/min	4 mg/kg once every 24 hours	6 mg/kg once every 24 hours
<30 mL/min, including hemodialysis and CAPD	4 mg/kg once every 48 hours*	6 mg/kg once every 48 hours*

*When possible, administer Daptomycin following the completion of hemodialysis on hemodialysis days.

INSTRUCTIONS FOR USE

Preparation of Daptomycin for Administration

Daptomycin is supplied in single-dose vials, each containing 500 mg daptomycin as a sterile, lyophilized powder. The contents of a daptomycin for injection vial should be reconstituted, using aseptic technique, to 50 mg/mL as follows:

Note: To minimize foaming, AVOID vigorous agitation or shaking of the vial during or after reconstitution.

1. Remove the polypropylene flip-off cap from the daptomycin for injection vial to expose the central portion of the rubber stopper.
2. Wipe the top of the rubber stopper with an alcohol swab or other antiseptic solution and allow to dry. After cleaning, do not touch the rubber stopper or allow it to touch any other surface.
3. Slowly transfer 10 mL of 0.9% sodium chloride injection through the center of the rubber stopper into the daptomycin for injection vial, pointing the transfer needle toward the wall of the vial. It is recommended that a beveled sterile transfer needle that is 21 gauge or smaller in diameter, or a needleless device is used, pointing the transfer needle toward the wall of the vial.
4. Ensure that all of the daptomycin for injection powder is wetted by gently rotating the vial.
5. Allow the wetted product to stand undisturbed for 10 minutes.
6. Gently rotate or swirl the vial contents for a few minutes, as needed, to obtain a completely reconstituted solution.
7. Slowly remove reconstituted liquid (50 mg daptomycin/mL) from the vial using a beveled sterile needle that is 21 gauge or smaller in diameter.

Adults

Intravenous Infusion over a period of 30 minutes

- For IV infusion over a period of 30 minutes in adult patients, the appropriate volume of the reconstituted daptomycin for injection (concentration of 50 mg/mL) should be further diluted, using aseptic technique, into a 50 mL IV infusion bag containing 0.9% sodium chloride injection.

Pediatric Patients (1 to 17 Years of Age)

Intravenous Infusion over a period of 30 or 60 minutes

- For IV infusion over a period of 30 minutes in pediatric patients, reconstituted daptomycin for injection (concentration of 50 mg/mL) is further diluted, using aseptic technique, into a 50 mL IV infusion bag containing 0.9% sodium chloride injection. The infusion rate should be maintained at 1.67 mL/min over the 30 minute period.
- For IV infusion over a period of 60 minutes in pediatric patients, reconstituted daptomycin for injection (concentration of 50 mg/mL) is further diluted, using aseptic technique, into an IV infusion bag containing 25 mL of 0.9% sodium chloride injection. The infusion rate should be maintained at 0.42 mL/min over the 60 minute period.

Parenteral drug products should be inspected visually for particulate matter prior to administration.

No preservative or bacteriostatic agent is present in this product. Aseptic technique must be used in the preparation of final IV solution. Stability studies have shown that the reconstituted solution is stable in the vial for 12 hours at room temperature (25°C) and up to 48 hours if stored under refrigeration at 2 to 8°C(36 to 46°F).

The diluted solution is stable in the infusion bag for 12 hours at room temperature (25°C) and 48 hours if stored under refrigeration at 2 to 8°C(36 to 46°F). The combined storage time (reconstituted solution in vial and diluted solution in infusion bag) should not exceed 12 hours at room temperature (25°C) or 48 hours under refrigeration at 2 to 8°C(36 to 46°F).

Daptomycin vials are for single use only.

Compatible Intravenous Solutions

The compatible diluent for reconstitution is 0.9% sodium chloride injection and lactated Ringer's injection.

For IV infusion, reconstituted daptomycin for injection (concentration of 50 mg/mL) is further diluted, using aseptic technique, with 0.9% sodium chloride injection.

Reconstitute daptomycin for injection, as directed above, to a concentration of 50 mg/mL with 0.9% sodium chloride injection. Further dilute using aseptic technique with additional 0.9% sodium chloride injection to a final concentration in the range of 2.5 to 20 mg/mL (typically 10 mg/mL).

Vial Size	Nominal Concentration of Reconstituted Solution	Approximate Available Volume of Reconstituted Solution	Volume of Additional Diluent	Total Volume of Solution for Infusion	Nominal Concentration of Solution for Infusion
500 mg	50 mg/mL	10 mL	15 mL	25 mL	20 mg/mL
500 mg	50 mg/mL	10 mL	40 mL	50 mL	10 mg/mL
500 mg	50 mg/mL	10 mL	190 mL	200 mL	2.5 mg/mL

INCOMPATIBILITIES

Daptomycin is not compatible with dextrose-containing diluents.

Because only limited data are available on the compatibility of daptomycin with other IV substances, additives and other medications should not be added to daptomycin for injection single-dose vials or infusion bags, or infused simultaneously through the same IV line. If the same IV line is used for sequential infusion of different drugs, the line should be flushed with a compatible intravenous solution before and after infusion with daptomycin for injection.

USE IN SPECIFIC POPULATIONS

Pediatric

The safety and effectiveness of daptomycin for injection in patients 1 to 17 years are supported by evidence from adequate and well-controlled studies in adults, pharmacokinetic data in pediatric patients, and additional data from two prospective studies in pediatric patients 1 to 17 years of age with cSSSI and pediatric patients 2 to 17 years of age with Staphylococcus aureus Bloodstream Infections (bacteremia).

Elderly

No adjustment of daptomycin for injection dosage is warranted for elderly patients with CL_{cr} ≥30 mL/min.

Renal Impairment

Daptomycin is eliminated primarily by the kidneys; therefore, an adjustment of daptomycin for injection dosage interval is recommended for adult patients with CL_{cr} <30 mL/min, including patients receiving hemodialysis or CAPD. The recommended dosing regimen for these adult patients is 4 mg/kg (cSSSI) or 6 mg/kg (*S. aureus* bloodstream infections) once every 48 hours. Alternatively, adult patients on hemodialysis can be dosed three times per week. When possible, administer daptomycin for injection following the completion of hemodialysis on hemodialysis days. In adult patients with renal impairment, monitor both renal function and CPK more frequently than once weekly.

No dosage interval adjustment is required for adult patients with CL_{cr} ≥30 mL/min.

The dosage regimen for daptomycin for injection in pediatric patients with renal impairment has not been established.

Hepatic Impairment

No dosage adjustment is warranted when daptomycin for injection is administered to patients with mild to moderate hepatic impairment (Child-Pugh Class B). The pharmacokinetics of daptomycin in patients with severe hepatic impairment (Child-Pugh Class C) have not been evaluated.

Gender

No dosage adjustment is warranted based on gender when daptomycin for injection is administered.

Obesity

No adjustment of daptomycin dosage is warranted in obese patients.

CONTRAINDICATIONS

Daptomycin for Injection is contraindicated in patients with known hypersensitivity to daptomycin or to any of the excipients.

WARNINGS AND PRECAUTIONS

Anaphylaxis/Hypersensitivity Reactions

Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including Daptomycin. If an allergic reaction to Daptomycin occurs, discontinue the drug and institute appropriate therapy.

Pneumonia

Daptomycin should not be used for the treatment of pneumonia. It has been demonstrated in clinical studies that Daptomycin is not effective in the treatment of community-acquired pneumonia, due to binding to pulmonary surfactant and consequent inactivation.

Skeletal Muscle Effects

Increases in plasma CPK levels, muscular pains, weakness, and/or rhabdomyolysis have been reported during therapy with Daptomycin.

It is recommended that:

- Patients receiving Daptomycin be monitored for the development of muscle pain or weakness, particularly of the distal extremities.
- In patients who receive Daptomycin, CPK levels be measured at baseline and at regular intervals (at least weekly), and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment with Daptomycin.
- In adult patients with renal impairment, both renal function and CPK be monitored more frequently than once weekly.
- Daptomycin be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels greater than 1000 U/L (approximately 5 times upper limit of normal [ULN]) and in patients without reported symptoms who have marked elevations in CPK, with levels greater than 2000 U/L (≥10× ULN).
- Consideration be given to suspending agents associated with rhabdomyolysis, such as HMG- CoA reductase inhibitors, temporarily in patients receiving Daptomycin.

Peripheral Neuropathy

Physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving Daptomycin.

Pediatric patients younger than one year old should not be given Daptomycin due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) that were observed in neonatal dogs.

Eosinophilic Pneumonia

Eosinophilic pneumonia has been reported in patients receiving Daptomycin. In reported cases associated with Daptomycin, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates or organizing pneumonia. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting Daptomycin and improved when Daptomycin was discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms while receiving Daptomycin should undergo prompt medical evaluation, and Daptomycin should be discontinued immediately. Treatment with systemic steroids is recommended.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Tubulointerstitial Nephritis (TIN)

DRESS and TIN have been reported in post-marketing experience with daptomycin. Patients who develop fever, skin rash, peripheral eosinophilia and/or new or worsening renal impairment or other organ impairment while receiving Daptomycin should undergo medical evaluation. If DRESS and/or TIN are suspected, Daptomycin should be discontinued promptly and appropriate treatment instituted.

***Clostridium difficile*–Associated Diarrhea**

Clostridium difficile–associated diarrhea (CDAD) has been reported with the use of nearly all antibacterial agents, including Daptomycin. If CDAD is suspected or confirmed, Daptomycin may need to be discontinued and appropriate treatment instituted as clinically indicated.

Persisting or Relapsing *S. aureus* Bacteremia/Endocarditis

Patients with persisting or relapsing *S. aureus* bacteremia/endocarditis or poor clinical response should have repeat blood cultures. If a blood culture is positive for *S. aureus*, minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed using a standardized procedure, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibacterial regimen may be required.

Drug-Laboratory Test Interactions

False prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) have been observed when certain recombinant thromboplastin reagents are utilized for the assay (see Undesirable Effects, Drug-Laboratory Test Interactions).

Non-Susceptible Microorganisms

The use of antibacterials may promote the overgrowth of non-susceptible microorganisms. If superinfection occurs during therapy, take appropriate measures.

INTERACTIONS

Interactions with Other Medicinal Products

Daptomycin was studied in adult human drug-drug interaction studies with aztreonam, tobramycin, warfarin, simvastatin, and probenecid. Daptomycin had no effect on the pharmacokinetics of warfarin or probenecid, nor did these drugs alter the pharmacokinetics of daptomycin. The pharmacokinetics of daptomycin were not significantly altered by aztreonam.

Experience with the concomitant administration of Daptomycin and warfarin is limited. Studies of Daptomycin with anticoagulants other than warfarin have not been conducted. Monitor anticoagulant activity in patients receiving Daptomycin and warfarin for the first several days after therapy with Daptomycin is initiated.

Experience with the coadministration of HMG-CoA reductase inhibitors and Daptomycin in patients is limited; therefore, consider suspending use of HMG-CoA reductase inhibitors temporarily in patients receiving Daptomycin.

Although small changes in the pharmacokinetics of daptomycin and tobramycin were observed during coadministration by IV infusion over a 30-minute period using a Daptomycin dose of 2 mg/kg, the changes were not statistically significant. The interaction between daptomycin and tobramycin with a clinical dose of Daptomycin is unknown. Caution is warranted when Daptomycin is coadministered with tobramycin.

Drug-Laboratory Test Interactions

Clinically relevant plasma concentrations of daptomycin have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay. The possibility of an erroneously elevated PT/INR result due to interaction with a recombinant thromboplastin reagent may be minimized by drawing specimens for PT or INR testing near the time of trough plasma concentrations of daptomycin. However, sufficient daptomycin concentrations may be present at trough to cause interaction.

If confronted with an abnormally high PT/INR result in a patient being treated with daptomycin, it is recommended that clinicians:

1. Repeat the assessment of PT/INR, requesting that the specimen be drawn just prior to the next daptomycin dose (i.e., at trough concentration). If the PT/INR value obtained at trough remains substantially elevated above what would otherwise be expected, consider evaluating PT/INR utilizing an alternative method.
2. Evaluate for other causes of abnormally elevated PT/INR results.

PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. Daptomycin should be used during pregnancy only if the potential benefit outweighs the possible risk.

Excretion of daptomycin into milk of lactating animals has not been studied. Until more experience is gained, women should be instructed to avoid breast-feeding while receiving Daptomycin.

SIDE EFFECTS

Undesirable Effects

Reported adverse drug reactions are organized by system organ class, and the frequency categories for these adverse drug reactions are summarized in the table below:

Adverse Drug Reaction	Frequency Category
Blood and lymphatic system disorders	
Anemia	Common
Thrombocytosis	Uncommon
Eosinophilia	Uncommon
Leukocytosis	Uncommon
Cardiac disorders	
Supraventricular arrhythmia	Uncommon
Ear and labyrinth disorders	
Vertigo	Uncommon
Gastrointestinal disorders	
Gastrointestinal and abdominal pain	Common
Diarrhea	Common
Vomiting	Common
Flatulence, bloating, and distension	Common
Constipation	Common
Nausea	Common
Dyspepsia	Uncommon
Abdominal distension	Uncommon
General disorders and administration site conditions	
Asthenia	Common
Pyrexia	Common
Infusion site reaction	Common
Chills	Uncommon
Fatigue	Uncommon
Hepatobiliary disorders	
Jaundice	Rare
Infections and infestations	
Urinary tract infection	Common
Fungal infection	Common
Candida infection	Common
Fungemia	Uncommon
Investigations	
Blood creatine phosphokinase increased	Common
Liver function test abnormal (increased ALT, AST, or ALP)	Common
Blood creatinine increased	Uncommon
International Normalized Ratio increased	Uncommon
Blood lactate dehydrogenase increased	Uncommon
Prothrombin time prolonged	Rare
Metabolism and nutrition disorders	
Hyperglycemia	Uncommon
Electrolyte imbalance	Uncommon
Decreased appetite	Uncommon
Musculoskeletal, connective tissue, and bone disorders	
Limb pain	Common
Muscular weakness	Uncommon
Muscle pain	Uncommon
Arthralgia	Uncommon
Muscle cramps	Uncommon
Nervous system disorders	
Dizziness	Common
Headache	Common
Paresthesia	Uncommon
Tremor	Uncommon
Taste disorder	Uncommon
Eye irritation	Uncommon
Psychiatric disorders	
Anxiety	Common
Insomnia	Common
Renal and urinary disorders	
Renal impairment, including renal failure and renal insufficiency	Uncommon
Reproductive system and breast disorders	
Vaginitis	Uncommon
Skin and subcutaneous tissue disorders	
Pruritus	Common
Rash	Common
Urticaria	Uncommon
Vascular disorders	
Hypertension	Common
Hypotension	Common
Flushing	Uncommon

Other Undesirable Effects

The following adverse drug reactions, not listed above, have also been reported:

Blood and lymphatic system disorders

Thrombocytopenia

Immune system disorders

Hypersensitivity reactions, including, but not limited to, anaphylaxis, angioedema, drug reaction with eosinophilia and systemic symptoms (DRESS), and pulmonary eosinophilia

Infections and infestations

Clostridium difficile–associated diarrhea

Investigations

Myoglobin increased, platelet count decreased

Musculoskeletal, connective tissue, and bone disorders

Rhabdomyolysis

Nervous system disorders

Peripheral neuropathy

Renal and urinary disorders

Tubulointerstitial nephritis (TIN)

Respiratory, thoracic, and mediastinal disorders

Cough,

Eosinophilic pneumonia

Organizing pneumonia

Skin and subcutaneous tissue disorders

Vesiculobullous rash with or without mucous membrane involvement Acute generalized exanthematous pustulosis

SYMPTOMS AND TREATMENT OF OVERDOSE

In the event of overdose, supportive care is advised. Daptomycin is cleared slowly from the body by hemodialysis (approximately 15% of the administered dose is removed over 4 hours) and by peritoneal dialysis (approximately 11% of the administered dose is removed over 48 hours).

Effects on Ability to Drive and Use Machine

No information is available.

STORAGE CONDITION

Unopened vial: Store original packages at refrigerated temperatures (2°C – 8°C); avoid excessive heat.

After reconstitution: Chemical and physical stability of the reconstituted solution in the vial has been demonstrated for 12 hours at room temperature (25°C) and up to 48 hours if stored under refrigeration (2 to 8°C). Chemical and physical stability of the diluted solution in infusion bags has been established as 12 hours at room temperature (25°C) and 48 hours if stored under refrigeration at 2 to 8°C. The combined storage time (reconstituted solution in vial and diluted solution in infusion bag) must not exceed 12 hours at room temperature (25°C) or 48 hours at refrigeration (2 to 8°C).

SHELF LIFE

Unopened Vial: 2 years

After reconstitution: Chemical and physical stability of the reconstituted solution in the vial has been demonstrated for 12 hours at room temperature (25°C) and up to 48 hours if stored under refrigeration (2 to 8°C). Chemical and physical stability of the diluted solution in infusion bags has been established as 12 hours at room temperature (25°C) and 48 hours if stored under refrigeration at (2 to 8°C). The combined storage time (reconstituted solution in vial and diluted solution in infusion bag) must not exceed 12 hours at room temperature (25°C) or 48 hours at refrigeration (2 to 8°C).

PRESENTATION

BEDAPT 500mg (Daptomycin for Injection 500mg per vial) is packed in clear Type-I 10R/20mm tubular glass vial, stoppered with 20mm lyophilisation Type-I grey rubber bromobutyl closure or 20mm lyophilisation Igloo Type I ready to use grey bromobutyl rubber closure and sealed with 20mm flip top aluminium seal. Each vial is further packed in pre-printed carton along with package insert. Each vial contains Daptomycin 500mg.

MANUFACTURER

Biological E. Limited,
Plot No. 4, Sy. No. 542/P,
Biotech Park, Phase-II, Kolthur Village,
Shameerpet Mandal, Medchal,
Telangana, 500078, India.

PRODUCT REGISTRATION HOLDER

Unimed Sdn. Bhd.
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur, Malaysia.

XXXXXXXX

DATE OF REVISION

01/11/2023

Front

Back

Artwork Detail Label			
Product	BEDAPT 500mg (Daptomycin for Injection 500mg per vial)	**Buyer/Country**	Malaysia
Component	Printed Literature	**Design/Style**	Folded Literature
Dimensions	Open Size: L165 x H420 mm	**Primary Pack Style**	Vial Pack
Substrate/Specification	40 GSM Bible Paper		
Colour Shades	Black C	**No. of Colours**	1
Item Code	xxxxxxxx	**Old Item Code**	----- NA ------
Miniature/Linear/2D Pharmacode No	----- NA ------		
Artwork Version	00		