

2004 Clinical Findings: CUBICIN[®] Outcomes Registry and Experience (CORE) Database



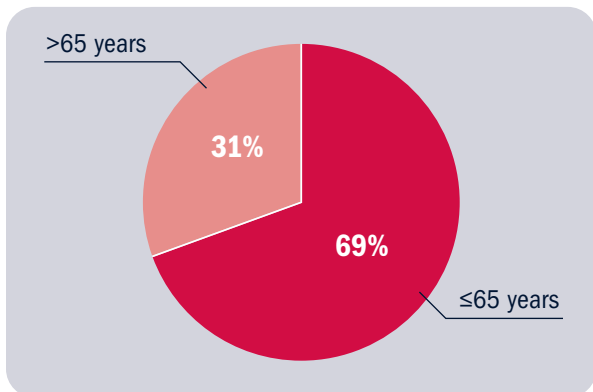
- Postmarketing data analysis of patients receiving CUBICIN (daptomycin for injection) in complicated skin and skin structure infections (cSSSI)
 - In 2004, 45 clinical sites in the United States submitted data
 - Additional data to be presented by year-end 2005
- Inclusion criteria:
 - Any combination of cSSSI types: surgical site, major abscess, wound, or ulcer
 - Skin infections complicated by underlying diseases (eg, diabetes mellitus, peripheral vascular disease, immunosuppressed host)



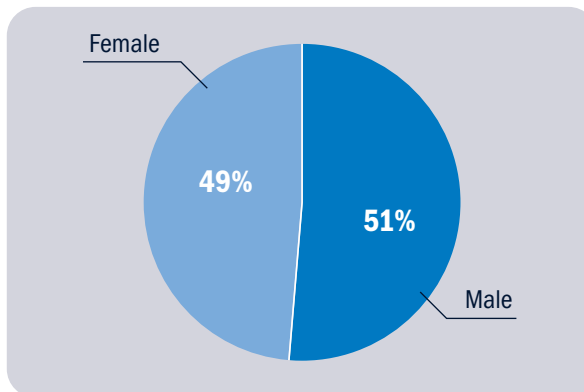
96%

CORESM cSSSI* patient characteristics (n=383)

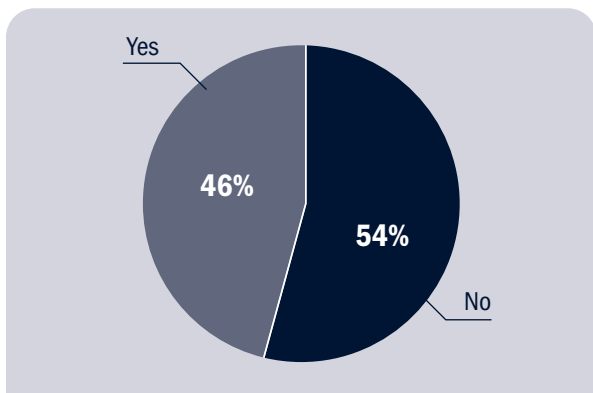
Age



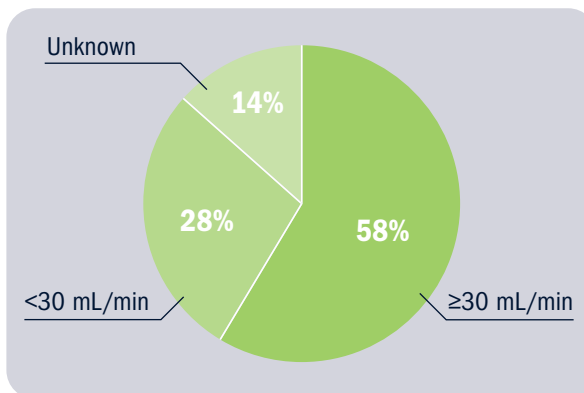
Gender



Concomitant Antibiotic Therapy



Baseline Renal Function (CL_{CR})



Concomitant antibiotics (>10%; n=176)[†]

Fluoroquinolone	24.4%
Cephalosporin	24.4%
Penicillin	17.7%
Carbapenem	11.4%

- Over 70% of patients had received previous antibiotic therapy

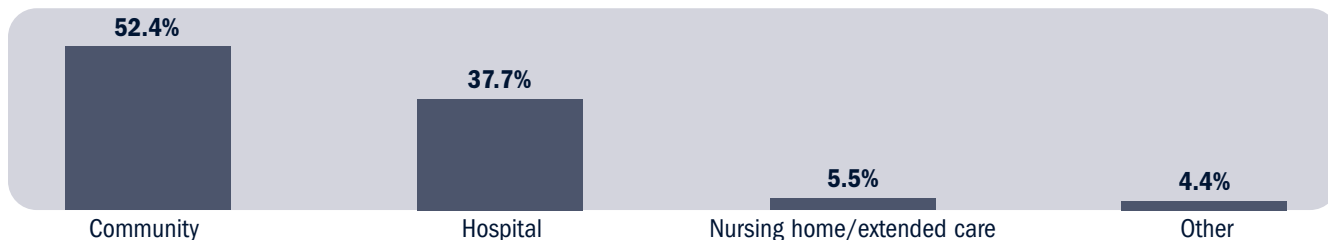
*Complicated skin and skin structure infection.

[†]Identified concomitant antibiotics also included aztreonam, clindamycin, vancomycin, rifampin, and others.

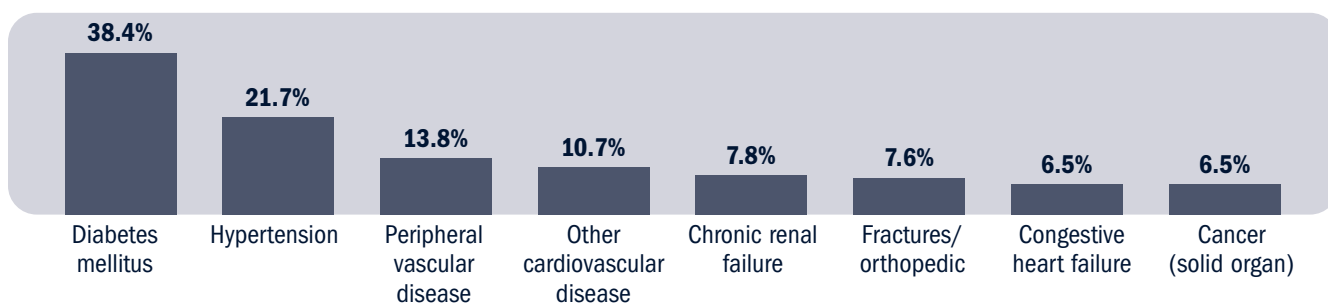


CORESM monitors a range of prior patient locations, comorbidities, cSSSI types, and pathogens

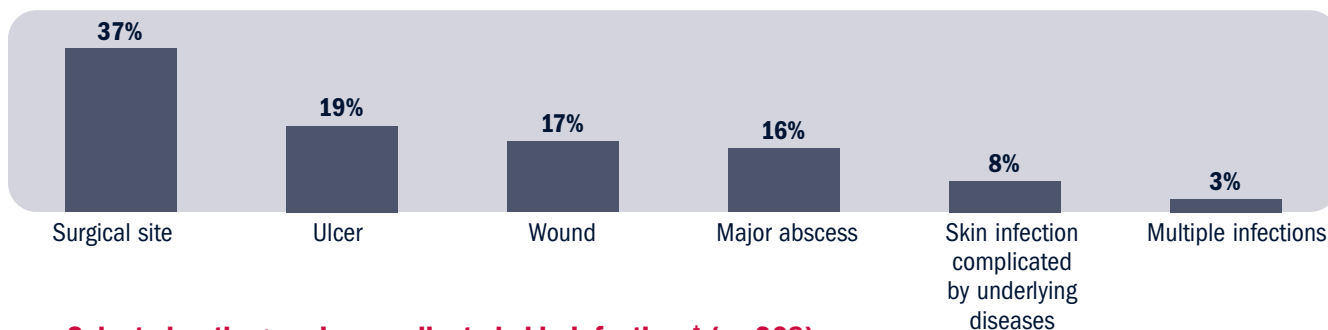
cSSSI patient location 48 hours prior to receiving CUBICIN[®] (daptomycin for injection) (n=382)



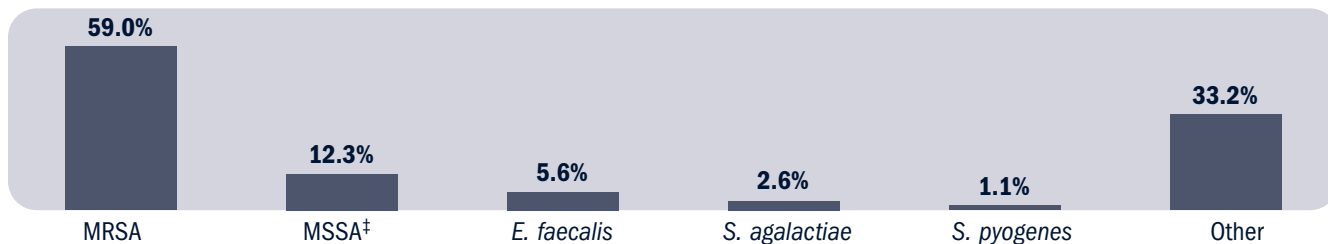
cSSSI patient underlying diseases (>5%)* (n=383)



Types of cSSSI in patients receiving CUBICIN (n=383)



Selected pathogens in complicated skin infections[†] (n=268)



■ Pathogens were isolated prior to starting CUBICIN therapy in a majority of infections

*Many individuals had several comorbidities.

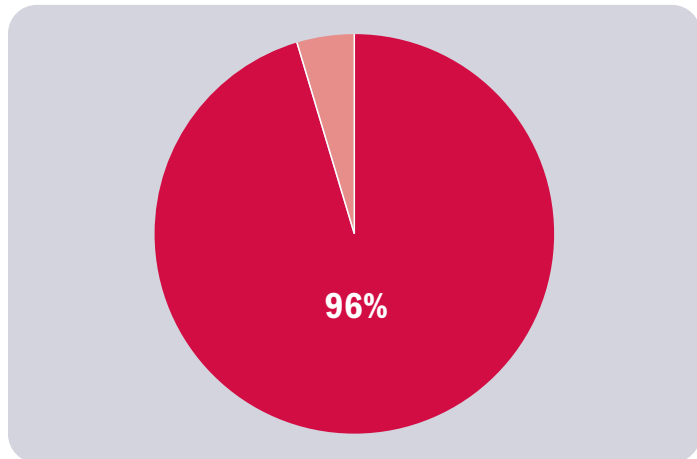
[†]305 pathogens in 268 patients isolated before CUBICIN therapy. Many individuals had several pathogens identified.

[‡]Includes MSSA and unknown methicillin susceptibility.



CORESM documents clinical outcomes in cSSSI registry patients* receiving CUBICIN[®]

Overall clinical success† (n=343)



Overall days of CUBICIN (daptomycin for injection) therapy

Mean duration of total therapy	18.5 days (n=342)
Mean duration to clinical response	5.3 days (n=251)

*Includes all patients with a reported clinical outcome. The number of nonevaluable patients (outcomes not reported) is 40.

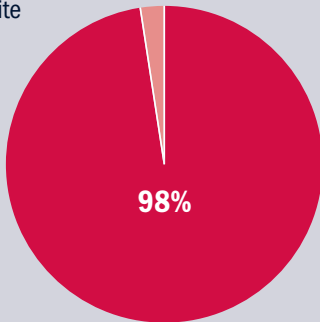
†Clinical success defined as cure or improvement. Patients that are not a success are defined as a clinical failure.



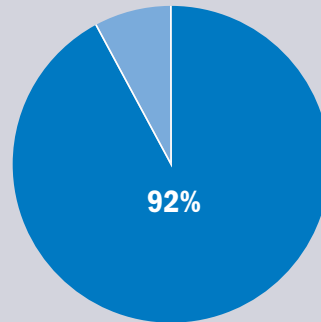
CORESM documents clinical outcomes in cSSSI registry patients* receiving CUBICIN[®]

Clinical success[†] by cSSSI types

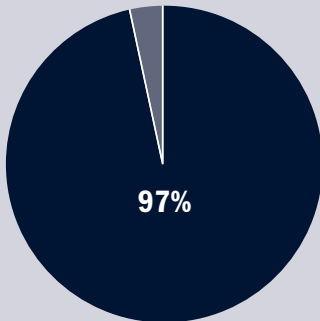
Surgical site
(n=129)



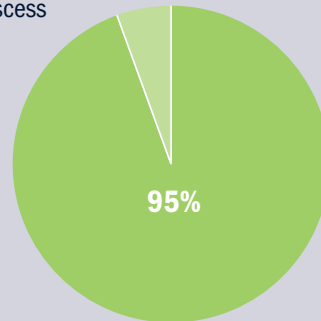
Ulcer
(n=62)



Wound
(n=60)



Major abscess
(n=55)



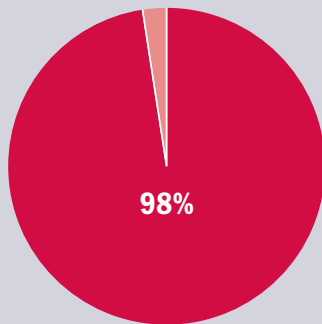
*Includes all patients with a reported clinical outcome. The numbers of nonevaluable patients (outcomes not reported) by cSSSI type are: 18 (surgical site); 9 (ulcer); 4 (wound); 5 (major abscess).

[†]Clinical success defined as cure or improvement. Patients that are not a success are defined as a clinical failure.

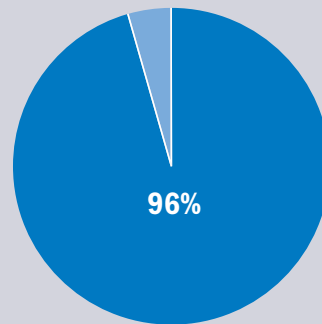
CORESM documents clinical outcomes in cSSSI registry patients* receiving CUBICIN[®]

Clinical success[†] by selected pathogens

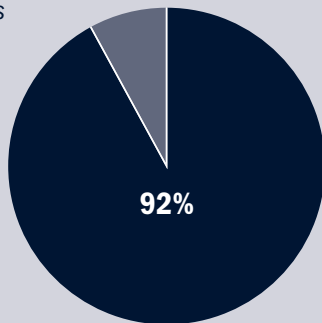
MRSA
(n=130)



MSSA
(n=25)



E. faecalis
(n=12)



*Includes all patients with a reported clinical outcome. The numbers of nonevaluable patients (outcomes not reported) by pathogen type are: 13 (MRSA); 4 (MSSA); 2 (*E. faecalis*).

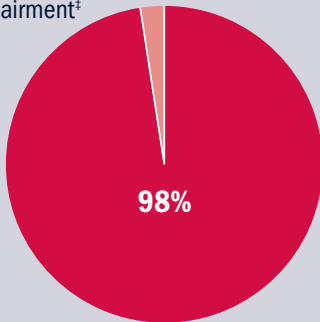
[†]Clinical success defined as cure or improvement. Patients that are not a success are defined as a clinical failure.



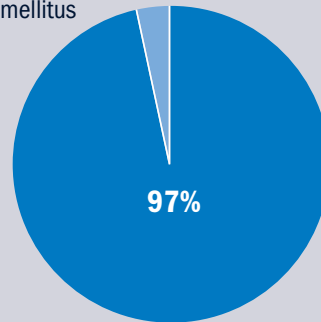
CORESM documents clinical outcomes in cSSSI registry patients* receiving CUBICIN[®]

Clinical success[†] by complicating comorbidities

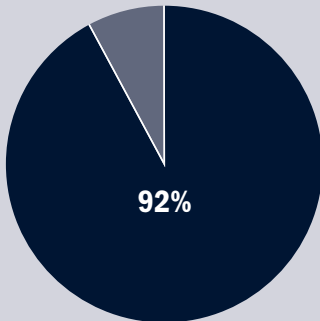
Renal impairment[‡]
(n=97)



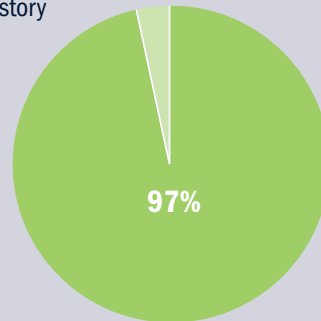
Diabetes mellitus
(n=133)



Peripheral vascular disease
(n=50)



Cancer history
(n=29)



*Includes all patients with a reported clinical outcome. The numbers of nonevaluable patients (outcomes not reported) by complicating comorbidities are: 12 (renal impairment); 14 (diabetes mellitus); 3 (peripheral vascular disease); 4 (cancer history).

[†]Clinical success defined as cure or improvement. Patients that are not a success are defined as a clinical failure.

[‡]Creatinine clearance <30 mL/min.

2004 CORESM Clinical Findings

CORE documents clinical outcomes in cSSSI registry patients* receiving CUBICIN[®]

- CORE is a retrospective, multicenter registry designed to collect data on patients who have received CUBICIN (daptomycin for injection)
- In 2004, 45 clinical sites in the United States submitted data
- In cSSSI registry patients, there was a range of infections, including surgical site infections, major abscesses, wounds, and ulcers
- In cSSSI registry patients with pathogens identified, a range of pathogens were isolated (MRSA isolated in 59% of patients)
- Overall clinical success[†] for cSSSI registry patients was 96%, and mean duration to clinical response was 5.3 days
- Clinical success[†] rates for cSSSI registry patients by cSSSI types (including surgical site, ulcer, wound, and major abscess) ranged from 92%–98%
- Clinical success[†] rates for cSSSI registry patients due to various pathogens (including MRSA, MSSA, and *E. faecalis*) ranged from 92%–98%
- Clinical success[†] rates for cSSSI registry patients with complicating comorbidities (including renal impairment, diabetes, peripheral vascular disease, and history of cancer) ranged from 92%–97%

*Includes all patients with a reported clinical outcome. The number of nonevaluable patients (outcomes not reported) is 40.

†Clinical success defined as cure or improvement. Patients that are not a success are defined as a clinical failure.

CUBICIN is indicated for the treatment of complicated skin and skin structure infections caused by susceptible strains of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus pyogenes*, *S. agalactiae*, *S. dysgalactiae* subsp *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible strains only).

CUBICIN is not indicated for the treatment of pneumonia.

Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. CPK levels should be monitored weekly, and any unexplained elevations should be monitored more frequently.

CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevation >1000 U/L, or in patients without reported symptoms who have marked elevation in CPK (≥10x ULN).

Most adverse events reported in clinical trials were mild or moderate in intensity. The most common adverse events were constipation, nausea, injection site reactions, and headaches.

Please see enclosed full prescribing information.

If you have a medical inquiry related to CUBICIN, please call **1-866-RX-DAPTO** (1-866-793-2786) 8:30 a.m. to 5:00 p.m. ET, Monday through Friday.



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