- *Streptococcus pneumoniae* bacteremia

The results of this analysis are shown in Table 11. Age ≥50 was the most common risk factor in the higher-risk group.

Table 11. Post-hoc Analysis of Clinical Cure Rates in Patients with Community-Acquired Bacterial Pneumonia Based on Risk of Mortality[a]

	TYGACIL n/N (%)	Levofloxacin n/N (%)	95% CI[b]
Study 308[c]			
CE			
Higher risk			
Yes	93/103 (90.3)	84/102 (82.4)	(-2.3, 18.2)
No	32/35 (91.4)	52/54 (96.3)	(-20.8, 7.1)
c-mITT			
Higher risk			
Yes	111/142 (78.2)	100/134 (74.6)	(-6.9, 14)
No	38/49 (77.6)	58/69 (84.1)	(-22.8, 8.7)
Study 313			
CE			
Higher risk			
Yes	95/107 (88.8)	68/85 (80)	(-2.2, 20.3)
No	33/37 (89.2)	48/51 (94.1)	(-21.1, 8.6)
c-mITT			
Higher risk			
Yes	112/134 (83.6)	93/120 (77.5)	(-4.2, 16.4)
No	58/69 (84.1)	70/80 (87.5)	(-16.2, 8.8)

[a] Patients at higher risk of death include patients with any one of the following: ≥50 year of age; PSI score ≥3; or bacteremia due to *Streptococcus pneumoniae*
[b] 95% confidence interval for the treatment difference
[c] After at least 3 days of intravenous therapy, a switch to oral levofloxacin (500 mg daily) was permitted for both treatment arms in Study 308.

15 REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically – 8th ed. Approved Standard, CLSI document M07-A8, CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898. January 2009.

2. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Disk Diffusion Susceptibility Tests – 10th ed. Approved Standard, CLSI document M02-A10, CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898. January 2009.

3. Clinical and Laboratory Standards Institute (CLSI). Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria – 7th ed. Approved Standard, CLSI document M11-A7, CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898. January 2007.

4. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing – 19th Informational Supplement. Approved Standard, CLSI document M100-S19, CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898. January 2009.

16 HOW SUPPLIED/STORAGE AND HANDLING

TYGACIL (tigecycline) for injection is supplied in a single-dose 5 mL glass vial containing 50 mg tigecycline lyophilized powder for reconstitution.

Supplied 10 vials/box. NDC: 0008-4990-02

Prior to reconstitution, TYGACIL should be stored at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Once reconstituted, TYGACIL may be stored at room temperature for up to 24 hours (up to 6 hours in the vial and the remaining time in the intravenous bag). Alternatively, TYGACIL mixed with 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP may be stored refrigerated at 2° to 8°C (36° to 46°F) for up to 48 hours following immediate transfer of the reconstituted solution into the intravenous bag. Reconstituted solution must be transferred and further diluted for intravenous infusion.

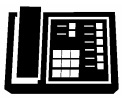
U.S. Patent Numbers: RE40086; RE40183; 5,284,963; 5,530,117; 5,675,030; and 7,365,087.

17 PATIENT COUNSELING INFORMATION

- Patients should be counseled that antibacterial drugs including TYGACIL should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TYGACIL is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by TYGACIL or other antibacterial drugs in the future.

- Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

This product's label may have been updated. For current package insert and further product information, please visit www.wyeth.com or call our medical communications department toll-free at 1-800-934-5556.



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(Update Rev Date)