

Benefit/Risk & Conclusion

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Gemifloxacin

Important Treatment Option in ABS

- Important burden of disease in ABS
- Safety
- Efficacy
- Risk/Benefit
- Risk Management

A Changing Paradigm for ABS Treatment

Using more active agent:

- Minimizes antibiotic resistance
- Protects drug class
- Benefits the patient

Gemifloxacin

Minimizes Risk of Drug Resistance

- High *in vitro* activity
- Favorable pharmacokinetics
- Active against *S. pneumoniae*
- Active against MDRSP
- Least likely fluoroquinolone to select for resistance to *S. pneumoniae*

Gemifloxacin Proven Efficacious in 5-Day ABS Treatment

- Large state-of-the-art clinical trial program
- High clinical response
 - 87% - 90% overall clinical cure rate
 - 87% - 90% clinical cure rate in large bacteriological evaluable population
- Comparable to other antibiotics previously approved for ABS

Effective Antibiotic Treatments for ABS

	Dose	Frequency	Duration
Amoxicillin-clavulanate*	2 g – 125 mg	2X	10d
Cefdinir*	600 mg	1X	10d
Cefpodoxime proxetil	200 mg	2X	10d
Cefuroxime axetil*	250 mg	2X	10d
Levofloxacin*	750 mg	1X	5d
Moxifloxacin	400 mg	1X	10d
Telithromycin	800 mg	1X	5d

* Found effective in pre- and post-treatment sinus aspirate and culture studies

Adapted from Gwaltney, Jack M., Jr., MD, Sinus. In: Mandell, G.L., MD, Bennett, J.E., MD, Dolin, R., MD, *Principles and Practice of Infectious Diseases, 6th Edition*; 2005: chap. 55.

Gemifloxacin

Clinically Manageable, Benign Drug Rash

- Self-limiting
- Mild-to-moderate in severity
- Low cross sensitization (5%)
- No sub-clinical sensitization
- Low rash rate at indicated duration
- No confirmed SJS
- No TEN

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Favorable Safety Profile

- Low rate of SAEs
- Low rate of hepatic and cardiac events
- No confirmed Torsades de Pointes
- No glucose regulation problems
- A very low rate of discontinuation
- No significant drug-drug interactions

Gemifloxacin's Overall Safety Comparable to Other ABS Drugs

- Clinical trial data (approved comparators)
- AERS database
- Summary Basis of Approvals

Risk Minimization

Most Patients Receive One Fixed-Dose Course of Gemifloxacin

- 4,910 real-world gemifloxacin patients so far
- 92.8% received a single fixed-dose prescription
- 3.1% of courses refilled

Gemifloxacin

Continuing Risk Minimization Program

- Moving to a 5-day, fixed-dose franchise
 - AECB 5 days
 - CAP 7 days ➔ 5 days
 - sNDA pending
 - (ABS 5 days)
- Continuing physician education program
- Continuing to publish on safety issues

Conclusion

Gemifloxacin is an appropriate drug
for the treatment of ABS