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Erratum to the Factive® (gemifloxacin mesylate) Tablets
For the Treatment of Acute Bacterial Sinusitis
Briefing Document

NDA #21-158, S-006

Prepared by Oscient Pharmaceuticals Corporation

Pages 58-60, the bacteriologic eradication rates for "all pathogens" were revised based on the discovery of a programming calculation error.

- Page 58, paragraph 1, line 2 should read: "At follow-up, 92.5% (135/146) of initial pathogens in the gemifloxacin group and 94.0% (142/151) in the cefuroxime group were eradicated or presumed eradicated."

- Page 59, paragraph 1, line 3 should read: "At follow-up, 92.5% (135/146) of initial pathogens in the gemifloxacin 7-day group and 93.2% (288/309) in the gemifloxacin 5-day group were eradicated or presumed eradicated."

- The corrected Tables 27 and 28 are as follows:

Table 27: Clinical and Bacteriological Efficacy by Pre-Therapy Pathogens at Follow-Up: Study 009 (Bacteriology PP Population)

	Gemifloxacin 320 mg od 7 days		**Cefuroxime 250 mg bid 10 days**	
Pre-Therapy Pathogen	**Clinical Success**	**Bacteriological Eradication***	**Clinical Success**	**Bacteriological Eradication***
Outcome at Follow-Up	**N+=133 n/N** (%)**	**N+=133 n/N** (%)**	**N+=138 n/N** (%)**	**N+=138 n/N** (%)**
All pathogens	133/146 (91.1)	135/146 (92.5)	137/151 (90.7)	142/151 (94.0)
S. pneumoniae	54/55 (98.2)	54/55 (98.2)	54/58 (93.1)	54/58 (93.1)
MDRSP***	14/14 (100.0)	14/14 (100.0)	12/15 (80.0)	12/15 (80.0)
H. influenzae	26/28 (92.9)	26/28 (92.9)	30/31 (96.8)	31/31 (100.0)
S. aureus	12/14 (85.7)	13/14 (92.9)	8/9 (88.9)	8/9 (88.9)
K. pneumoniae	12/14 (85.7)	12/14 (85.7)	17/18 (94.4)	17/18 (94.4)
M. catarrhalis	7/7 (100.0)	7/7 (100.0)	5/5 (100.0)	5/5 (100.0)
E. coli	2/3 (66.7)	2/3 (66.7)	2/3 (66.7)	3/3 (100.0)

Table 28: Clinical and Bacteriological Efficacy by Pre-Therapy Pathogens at Follow-Up: Study 009 and Studies 206 and 333 Combined (Bacteriology PP Population)

	Study 009 Gemifloxacin 320 mg od 7 days		Studies 206 and 333 Gemifloxacin 320 mg od 5 days	
Pre-Therapy Pathogen	**Clinical Success**	**Bacteriological Eradication***	**Clinical Success**	**Bacteriological Eradication***
Outcome at Follow-Up	**N+=133 n/N** (%)**	**N+=133 n/N** (%)**	**N+=267 n/N** (%)**	**N+=267 n/N** (%)**
All pathogens	133/146 (91.1)	135/146 (92.5)	285/309 (92.2)	288/309 (93.2)
S. pneumoniae	54/55 (98.2)	54/55 (98.2)	96/103 (93.2)	97/103 (94.2)
MDRSP***	14/14 (100.0)	14/14 (100.0)	24/24 (100.0)	24/24 (100.0)
H. influenzae	26/28 (92.9)	26/28 (92.9)	51/53 (96.2)	51/53 (96.2)
S. aureus	12/14 (85.7)	13/14 (92.9)	13/16 (81.3)	14/16 (87.5)
K. pneumoniae	12/14 (85.7)	12/14 (85.7)	7/8 (87.5)	7/8 (87.5)
M. catarrhalis	7/7 (100.0)	7/7 (100.0)	17/17 (100.0)	17/17 (100.0)
E. coli	2/3 (66.7)	2/3 (66.7)	11/12 (91.7)	11/12 (91.7)

Page 68, the number of SAEs of rash for the 5-day ABS gemifloxacin sub-group should be 1 (<0.1%) instead of 0 (0%). This single event is not coded by the preferred term "rash" and was inadvertently omitted from the subgroup, though it is included in the number of rash SAEs (n=7) for the total gemifloxacin safety population (n=8119).

- The corrected Table 31 is as follows:

Table 31: Incidence of Adverse Experiences of Rash for Both Treatment Groups

Type of AE	Treatment Group					
	Gemifloxacin 320 mg PO N=8119		5 Day ABS Gemifloxacin 320 mg PO N=1122		All Comparators N=5248	
	N	**(%)**	**N**	**(%)**	**n**	**(%)**
Rash*	283	(3.5)	29	(2.6)	59	(1.1)
SAE of rash*	7	(0.1)	1	(<0.1)	1	(<0.1)
Rash* leading to withdrawal	66	(0.8)	3	(0.3)	15	(0.3)

*Rash includes the preferred terms rash, rash erythematous, rash maculo-papular, and rash pustular.

- Paragraph 2, line 2: "In the 5-day ABS gemifloxacin group, there were no SAEs of rash." should read "In the 5-day ABS gemifloxacin group, there was one rash SAE (1/1122 or <0.1%)."