

## Erratum to NDA 22-034 Clinical Review

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Clinical Review Page 27 [PDF Page 30] - last paragraph, before section 7.1.3, starting “Other SAEs considered ...” states that the annual report of the oral formulation under IND listed two cases of ventricular fibrillation. The correct number is one case of ventricular fibrillation that was reported by this annual report.

Clinical Review Page 19 [PDF Page 32] - Table 19. Cardiac Events Occurring within 2 Hours of Study Drug Infusion by Severity from All Studies

This table is to be replaced by the following table because of an error in the number of ventricular fibrillation cases, on two doses of Vernakalant, that were characterized as life-threatening.

Severity of events	Placebo N = 339	Vernakalant one dose N = 258	Vernakalant two doses N = 520	All Vernakalant N = 778
<b>Life Threatening</b>				
Ventricular fibrillation	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Bradycardia	1 (0.3%)	2 (0.78%)	0 (0%)	2 (0.26%)
Complete AV block	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
Sinus arrest	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
<b>Severe/Moderate</b>				
Hypotension	2 (0.6%)	10 (3.88%)	10 (1.92%)	20 (2.57%)
Bradycardia	0 (0%)	8 (3.1%)	3 (0.58%)	11 (1.41%)
Bundle branch block left	0 (0%)	1 (0.4%)	2 (0.4%)	3 (0.4%)
Atrial fibrillation	2 (0.6%)	1 (0.4%)	4 (0.77%)	5 (0.64%)
AFL	0 (0%)	2 (0.78%)	3 (0.58%)	5 (0.64%)
Hypertension	0 (0%)	0 (0%)	2 (0.38%)	2 (0.26%)
Atrial tachycardia	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Electromechanical dissociation	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Palpitations	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Sinus arrest	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Supraventricular tachycardia	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Ventricular extrasystoles	0 (0%)	1 (0.4%)	1 (0.2%)	2 (0.26%)
Ventricular fibrillation	0 (0%)	0 (0%)	1 (0.2%)	1 (0.1%)
Angina pectoris	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)
Bundle branch block right	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
Atrial dilatation	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
Mitral valve incompetence	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)
Tachycardia	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
Ventricular bigeminy	0 (0%)	1 (0.4%)	0 (0%)	1 (0.1%)
Ventricular tachycardia	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)

**Erratum to NDA 22-034 Clinical Review (continued)**

Clinical Review Page 56 [PDF Page 59] - Table 27. Ventricular Arrhythmia from All Sources in Subjects from ACTI, ACTIII within Two Hours

Because of inaccurate numbers, this table is to be replaced by the table below.

	<b>Placebo N=159</b>	<b>One dose N=99</b>	<b>Two Doses N=132</b>	<b>RSD123 Any Dose N=231</b>
Any ventricular arrhythmia	26 (16.4%)	16 (16.2%)	22 (16.7%)	38 (16.5%)
V-tach, all	14 (8.8%)	11 (11.1%)	15 (11.4%)	26 (11.3%)
Non-sustained V-Tach	10 (6.3%)	4 (4%)	10 (7.6%)	14 (6.1%)
Ventricular tachycardia	4 (2.5%)	7 (7.1%)	4 (3%)	11 (4.8%)
Sustained monomorphic V-tach	0 (0%)	0 (0%)	1 (0.8%)	1 (0.4%)
Ventricular bigeminy	0 (0%)	1 (1%)	0 (0%)	1 (0.4%)
Ventricular fibrillation	0 (0%)	0 (0%)	1 (0.8%)	1 (0.4%)
Ventricular Flutter	0 (0%)	0 (0%)	1 (0.8%)	1 (0.4%)
Ventricular rhythm >= 5 beats	1 (0.6%)	0 (0%)	1 (0.8%)	1 (0.4%)
Other rhythm	11 (6.9%)	4 (4%)	4 (3%)	8 (3.5%)

“Non-sustained V-Tach” includes “NON-SUSTAINED VENTRICULAR TACHYCARDIA“, “UNSUSTAINED MONOMORPHIC V-TACH”, and “UNSUSTAINED POLYMORPHIC V-TACH” as coded in the varrhyth.xpt dataset;

“Ventricular tachycardia” includes “VENTRICULAR TACHYCARDIA”, “VENTRICULAR TACHYCARDIA (V-TACH)”, and “TACHYCARDIA” as coded in the varrhyth.xpt dataset;

“V-Tach, all” includes all of the above plus “SUSTAINED MONOMORPHIC V-TACH” as coded in the varrhyth.xpt dataset;

Clinical Review Page 56 [PDF Page 59] - Paragraph under Table 27 is to be replaced by the following paragraph:

“The numbers are small, but the rate of non-specified ventricular tachycardia (coded in the varrhyth.xpt dataset as “VENTRICULAR TACHYCARDIA”, “VENTRICULAR TACHYCARDIA (V-TACH)”, and “TACHYCARDIA) almost doubled on Vernakalant compared to placebo. This excess is accounted for by the subjects who received one dose only.”