

Annex 1: UK Spontaneous Suspected Adverse Drug Reaction reports for Zoledronic Acid and Cardiac disorder SOC

Case Count	Drug Brand	Dose Number	Dose Unit	Start Date of Drug	Stop Date of Drug	Reaction MedDRA Cardiac PT Name	Outcome Of Reaction
1	ZOMETA			01/07/2005	13/07/2005	Bradycardia	not recovered/not resolved/ongoing
2	ZOMETA			01/01/2000		Myocardial infarction	recovering/resolving
3	ZOMETA			07/02/2005	27/07/2005	Bradycardia	recovered/resolved
4	ZOMETA			01/01/2003	29/08/2003	Angina pectoris	recovered/resolved
5	ZOMETA					Palpitations	recovered/resolved
6	ZOLEDRONIC ACID			18/07/2008		Bradycardia	recovering/resolving
7	ZOMETA			15/10/2008		Myocardial ischaemia	fatal
8	ZOLEDRONIC ACID	5	mg	02/02/2009	02/02/2009	Tachycardia	recovered/resolved
9	ACLASTA	5	mg	01/10/2008	01/10/2008	Atrial fibrillation	recovering/resolving
10	ACLASTA					Mitral valve incompetence	recovered/resolved with sequelae
						Atrial fibrillation	recovered/resolved with sequelae
						Palpitations	recovered/resolved with sequelae
11	ZOLEDRONIC ACID	4	mg			Atrial fibrillation	unknown
12	ACLASTA	5	mg	25/07/2008	25/07/2008	Atrial fibrillation	recovered/resolved
						Supraventricular tachycardia	recovered/resolved
13	ACLASTA					Atrial fibrillation	recovered/resolved
14	ZOLEDRONIC ACID	5	mg	11/05/2010	11/05/2010	Palpitations	recovered/resolved
15	ZOMETA					Myocardial infarction	fatal
16	ZOMETA	3	mg	13/02/2007		Bradycardia	recovered/resolved
17	ACLASTA					Atrial fibrillation	recovered/resolved
						Palpitations	recovered/resolved
18	ACLASTA					Palpitations	recovering/resolving
19	ZOMETA	4	mg	28/09/2007	28/09/2007	Supraventricular tachycardia	recovering/resolving
20	ZOMETA	4	mg	30/11/2007		Tachycardia	recovering/resolving
21	ZOMETA	4	mg	29/11/2007		Tachycardia	recovering/resolving
22	ZOMETA	3	DF	01/12/2004	01/12/2004	Atrial fibrillation	recovered/resolved with sequelae
23	ZOMETA			01/06/2007		Cardiac sarcoidosis	unknown
24	ACLASTA					Bradycardia	unknown
						Atrial fibrillation	unknown
25	ZOLEDRONIC ACID			03/03/2008	03/03/2008	Atrial fibrillation	not recovered/not resolved/ongoing

26	ACLASTA	5	mg	27/02/2007	27/02/2007	Palpitations	not recovered/not resolved/ongoing
27	ACLASTA	5	mg	14/12/2010	14/12/2010	Angina pectoris	unknown
						Atrial fibrillation	recovered/resolved
						Palpitations	recovered/resolved
28	ZOMETA					Tachycardia	recovered/resolved
29	ACLASTA					Cardiac failure	additional fatal
						Atrial fibrillation	fatal
30	ACLASTA	5	mg	05/01/2009		Palpitations	recovering/resolving
31	ZOMETA					Cardiomyopathy	fatal
32	ZOLEDRONIC ACID	70	ml	10/05/2010	10/05/2010	Nodal arrhythmia	recovered/resolved
33	ACLASTA					Cardiac failure	fatal
						Atrial fibrillation	additional fatal
34	ACLASTA			25/02/2008		Palpitations	recovered/resolved
35	ZOLEDRONIC ACID					Atrial flutter	unknown
						Bifascicular block	unknown
						Dilatation atrial	unknown
						Pulmonary valve incompetence	unknown
						Bundle branch block right	unknown
						Tachyarrhythmia	unknown
						Tricuspid valve incompetence	unknown
						Left ventricular dysfunction	unknown
						Cardiac arrest	unknown
						Pulseless electrical activity	unknown
36	ACLASTA	5	mg	03/08/2011	03/08/2011	Tachycardia	unknown
37	ZOLEDRONIC ACID	5	mg	10/11/2009		Palpitations	recovered/resolved
38	ZOLEDRONIC ACID	4	mg	19/09/2012	19/09/2012	Tachycardia	recovered/resolved
39	ZOLEDRONIC ACID	5	mg	31/05/2013	31/05/2013	Myocardial infarction	fatal
40	ZOLEDRONIC ACID	5	mg	15/03/2013	15/03/2013	Tachycardia	recovering/resolving
41	ACLASTA			06/11/2013		Atrial fibrillation	unknown
42	ACLASTA			01/05/2013		Atrial fibrillation	recovered/resolved
43	ACLASTA					Myocardial infarction	unknown
44	ACLASTA					Atrial fibrillation	unknown
45	ZOMETA					Angina unstable	unknown
						Atrial fibrillation	unknown
46	ZOLEDRONIC ACID	5	mg	04/05/2016	04/05/2016	Bradycardia	recovered/resolved
47	ZOLEDRONIC ACID					Pericardial effusion	unknown
48	ZOMETA	3	mg			Heart valve incompetence	unknown
49	ZOLEDRONIC ACID	5	mg	11/11/2014		Atrial fibrillation	recovered/resolved

						Palpitations	not recovered/not resolved/ongoing
						Atrial fibrillation	recovered/resolved
						Palpitations	not recovered/not resolved/ongoing
						Atrial fibrillation	recovered/resolved
						Palpitations	not recovered/not resolved/ongoing
50	ZOMETA	4	mg			Cardiac disorder	unknown
51	ZOLEDRONIC ACID	5	mg	16/05/2019	15/05/2019	Tachycardia	not recovered/not resolved/ongoing
52	ZOMETA	4	mg	18/04/2018		Palpitations	unknown
53	ZOLEDRONIC ACID			10/03/2017	10/03/2017	Cardiac arrest	not recovered/not resolved/ongoing
54	ZOLEDRONIC ACID	3	mg	28/06/2017		Sinus tachycardia	unknown
55	ZOLEDRONIC ACID	5	mg	01/12/2016	18/01/2018	Ventricular fibrillation	not recovered/not resolved/ongoing
						Cardiac arrest	fatal
56	ZOLEDRONIC ACID	5	mg	27/06/2016	27/06/2016	Myocardial infarction	recovered/resolved with sequelae
57	ZOLEDRONIC ACID	5	mg			Atrial flutter	unknown
						Bifascicular block	unknown
						Dilatation atrial	unknown
						Atrial fibrillation	additional fatal
						Pulmonary valve incompetence	unknown
						Tricuspid valve incompetence	unknown
						Left ventricular dysfunction	unknown
						Tachycardia	recovered/resolved
						Cardiac arrest	fatal
						Pulseless electrical activity	additional fatal
58	ZOLEDRONIC ACID					Palpitations	recovering/resolving
59	ZOLEDRONIC ACID	4	mg	04/10/2017	07/10/2017	Tachycardia	recovered/resolved
60	ZOLEDRONIC ACID	1	DF	16/08/2016	16/08/2016	Atrial fibrillation	not recovered/not resolved/ongoing
						Palpitations	not recovered/not resolved/ongoing
61	ZOLEDRONIC ACID	2	mg	07/02/2018	07/02/2018	Tachycardia	recovered/resolved
62	ACLASTA			12/03/2018		Palpitations	unknown
63	ZOLEDRONIC ACID	5	mg	12/03/2018		Atrial fibrillation	not recovered/not resolved/ongoing

64	ZOLEDRONIC ACID	5	mg	01/03/2018	04/11/2020	Cardiac arrest	not recovered/not resolved/ongoing
65	ACLASTA	5	mg	02/11/2020		Cardiac failure	fatal
66	ZOLEDRONIC ACID					Cardiac arrest	not recovered/not resolved/ongoing
67	ZOLEDRONIC ACID	0	mg/kg			Cardiac ventricular thrombosis	unknown
						Tachycardia	unknown
68	ZOLEDRONIC ACID	0	mg/kg			Cardiac ventricular thrombosis	recovered/resolved
						Tachycardia	not recovered/not resolved/ongoing
						Cardiac ventricular thrombosis	recovered/resolved
						Tachycardia	not recovered/not resolved/ongoing
69	ZOLEDRONIC ACID					Cardiac ventricular thrombosis	recovered/resolved
						Mitral valve incompetence	recovered/resolved
						Left ventricular dysfunction	recovered/resolved
70	ZOLEDRONIC ACID	1	DF			Cardiac ventricular thrombosis	unknown
						Ventricular dysfunction	unknown
71	ZOLEDRONIC ACID	0	mg/kg			Cardiac ventricular thrombosis	recovered/resolved
72	ZOLEDRONIC ACID	5	mg	27/03/2019	27/03/2019	Cardiac failure congestive	unknown
73	ZOLEDRONIC ACID	5	mg	03/05/2019	03/05/2019	Palpitations	unknown
74	ZOLEDRONIC ACID			11/08/2020	11/08/2020	Bradycardia	recovered/resolved
75	ACLASTA	5	mg	01/12/2020	01/12/2020	Cardiac failure congestive	unknown
76	ZOLEDRONIC ACID					Sinus tachycardia	unknown
						Palpitations	unknown
77	ZOLEDRONIC ACID					Cardiac failure congestive	recovered/resolved
78	ZOLEDRONIC ACID					Atrial fibrillation	not recovered/not resolved/ongoing
79	ZOLEDRONIC ACID					Atrial fibrillation	not recovered/not resolved/ongoing
						Palpitations	not recovered/not resolved/ongoing
80	ACLASTA					Palpitations	recovering/resolving
81	ZOLEDRONIC ACID					Extrasystoles	recovering/resolving
						Atrial fibrillation	recovering/resolving
82	ZOLEDRONIC ACID					Bundle branch block left	recovered/resolved with sequelae
83	ZOLEDRONIC ACID					Acute myocardial infarction	unknown
84	ZOLEDRONIC ACID	5	mg	09/04/2024		Myocardial ischaemia	fatal
85	ZOLEDRONIC ACID					Myocardial infarction	unknown

						Cardiac disorder	unknown
86	ZOMETA					Bradycardia	recovering/resolving
87	ALTAN PHARMA ZOLEDRONIC ACID					Palpitations	recovering/resolving
88	ZOLEDRONIC ACID					Atrial fibrillation	not recovered/not resolved/ongoing
89	ZOMETA					Palpitations	recovered/resolved
90	ZOLEDRONIC ACID			06/03/2025		Palpitations	not recovered/not resolved/ongoing
91	ZOLEDRONIC ACID					Tachycardia	recovering/resolving
92	ZOLEDRONIC ACID			27/11/2025		Myocarditis	recovered/resolved
93	ZOLEDRONIC ACID			15/02/2024	15/02/2024	Palpitations	not recovered/not resolved/ongoing
94	ZOLEDRONIC ACID					Atrial fibrillation	recovered/resolved
95	ZOLEDRONIC ACID					Acute coronary syndrome	recovered/resolved