

Table 1 Adverse Reactions Occurring in $\geq 2\%$ of **EVENTITY-Treated Women in at Least One Study (Studies 1 and 2)**

Preferred Term	Study 1		Study 2	
	Placebo (N = 3576) n (%)	EVENTITY (N = 3581) n (%)	Alendronate (N = 2014) n (%)	EVENTITY (N = 2040) n (%)
Arthralgia	434 (12.1)	468 (13.1)	194 (9.6)	166 (8.1)
Headache	208 (5.8)	235 (6.6)	110 (5.5)	106 (5.2)
Muscle spasms	140 (3.9)	163 (4.6)	81 (4.0)	70 (3.4)
Edema peripheral	67 (1.9)	86 (2.4)	38 (1.9)	34 (1.7)
Asthenia	79 (2.2)	84 (2.3)	53 (2.6)	50 (2.5)
Neck pain	54 (1.5)	80 (2.2)	42 (2.1)	34 (1.7)
Insomnia	68 (1.9)	72 (2.0)	36 (1.8)	34 (1.7)
Paresthesia	62 (1.7)	72 (2.0)	34 (1.7)	29 (1.4)

Table 1: Common Adverse Reactions Reported in Postmenopausal Women with Osteoporosis*

Preferred term	TYMLOS (N=822) (%)	Placebo (N=820) (%)
Hypercalciuria	11	9
Dizziness	10	6
Nausea	8	3
Headache	8	6
Palpitations	5	0.4
Fatigue	3	2
Abdominal pain upper	3	2
Vertigo	2	2

* Adverse reactions reported in $\geq 2\%$ of TYMLOS-treated patients.

Orthostatic Hypotension

In the clinical trial of women with postmenopausal osteoporosis, the incidence of orthostatic blood pressure decline ≥ 20 mmHg systolic or ≥ 10 mmHg diastolic at 1 hour after the first injection was 4% in the TYMLOS group and 3% in the placebo group. At later time points the incidence was generally similar between the treatment groups. Adverse reactions of orthostatic hypotension were reported in 1% of patients receiving TYMLOS and 0.5% of patients receiving placebo. Dizziness was reported by more TYMLOS-treated patients (10%) compared to placebo (6%) [see *Warnings and Precautions* (5.2)].

Tachycardia

In women with postmenopausal osteoporosis, adverse reactions of tachycardia, including sinus tachycardia, were reported in 2% of patients receiving TYMLOS and 1% of patients in the placebo group. In 5 of the 13 patients receiving TYMLOS who experienced tachycardia, symptoms occurred within 1 hour of administration. TYMLOS has been associated with a dose-dependent increase in heart rate which developed within 15 minutes after injection and resolved in about 6 hours [see Clinical Pharmacology (12.2)].

Preferred Term	Prolia (N = 3886) n (%)	Placebo (N = 3876) n (%)
Back pain	1347 (34.7)	1340 (34.6)
Pain in extremity	453 (11.7)	430 (11.1)
Musculoskeletal pain	297 (7.6)	291 (7.5)

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Preferred Term	Prolia (N = 3886) n (%)	Placebo (N = 3876) n (%)
Hypercholesterolemia	280 (7.2)	236 (6.1)
Cystitis	228 (5.9)	225 (5.8)
Vertigo	195 (5.0)	187 (4.8)
Upper respiratory tract infection	190 (4.9)	167 (4.3)
Edema peripheral	189 (4.9)	155 (4.0)
Sciatica	178 (4.6)	149 (3.8)
Bone pain	142 (3.7)	117 (3.0)
Abdominal pain upper	129 (3.3)	111 (2.9)
Anemia	129 (3.3)	107 (2.8)
Insomnia	126 (3.2)	122 (3.1)
Myalgia	114 (2.9)	94 (2.4)
Angina pectoris	101 (2.6)	87 (2.2)
Rash	96 (2.5)	79 (2.0)
Pharyngitis	91 (2.3)	78 (2.0)
Asthenia	90 (2.3)	73 (1.9)
Pruritus	87 (2.2)	82 (2.1)
Flatulence	84 (2.2)	53 (1.4)
Spinal osteoarthritis	82 (2.1)	64 (1.7)
Gastroesophageal reflux disease	80 (2.1)	66 (1.7)
Herpes zoster	79 (2.0)	72 (1.9)