TYMLOS®
(abaloparatide) injection

REBUILD BONE WITH TYMLOS

Change the trajectory of osteoporosis for your patients.[1]

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

TYMLOS is indicated for the:

- treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.
- treatment to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

IMPORTANT SAFETY INFORMATION

Contraindications: TYMLOS is contraindicated in patients with a history of systemic hypersensitivity to abaloparatide or to any component of the product formulation. Reactions have included anaphylaxis, dyspnea, and urticaria.

Please see Important Safety Information throughout and full Prescribing Information here.

YOUR PATIENTS COULD BE AT IMMINENT RISK FOR FRACTURE

AACE/ACE guidelines define patients at very high risk for fracture based on*[2]:

T-score
- **–3.0 or worse**

Fracture
- **Recent** (<1 year)
- **Multiple** fractures
- History of **fracture while on osteoporosis treatment** or drugs causing skeletal harm

FRAX®

Very high fracture probability:
- **>30% major** osteoporosis fracture
- **>4.5% hip** fracture

High risk for falls

In addition, patients unable to use antiresorptive therapy or those that experience progressive bone loss while on antiresorptive therapy remain at elevated risk.

***When it's time to help change the trajectory of osteoporosis, it's time for TYMLOS.*[1]**

*AACE/ACE Guidelines are intended for postmenopausal women with osteoporosis.

AACE=American Association Of Clinical Endocrinologists, ACE=American College Of Endocrinology. FRAX=Fracture Risk Assessment Tool, used to estimate the risk of fracture in the next 10 years. FRAX is a registered trademark of the World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield, UK.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Osteosarcoma: It is unknown whether TYMLOS will cause osteosarcoma in humans. Osteosarcoma has been reported in patients treated with a PTH-analog in the post marketing setting; however, an increased risk of osteosarcoma has not been observed in observational studies in humans. There are limited data assessing the risk of osteosarcoma beyond 2 years of TYMLOS use. Avoid use of TYMLOS for patients at an increased baseline risk for osteosarcoma including patients with open epiphysis (pediatric and young adult patients); metabolic bone diseases other than osteoporosis, including Paget's disease of the bone; bone metastases or a history of skeletal malignancies; prior external beam or implant radiation therapy involving the skeleton; or hereditary disorders predisposing to osteosarcoma.

In postmenopausal women with osteoporosis TYMLOS SIGNIFICANTLY REDUCES VERTEBRAL AND NONVERTEBRAL FRACTURES.

ACTIVE STUDY DESIGN: Phase 3 randomized, double-blind, placebo- and active-controlled study in postmenopausal women with osteoporosis (N=2,463) aged 49 to 86 years who were randomized to receive TYMLOS 80 mcg (n=824) or placebo (n=821) or teriparatide 20 mcg (n=818) subcutaneously once daily for 18 months to assess efficacy and safety of abaloparatide injection.[1,3]

TYMLOS showed significant, clinically meaningful fracture risk reduction vs placebo.[1,3]

FRACTURE RISK REDUCTION AT 18 MONTHS[1]

PRIMARY ENDPOINT
NEW VERTEBRAL†

86%

Relative Risk Reduction

86% RRR in new vertebral fractures (*P*<0.0001; 95% CI: 61, 95) and 3.6% ARR (95% CI: 2.1, 5.4) at 18 months (fracture incidence: 0.6% TYMLOS vs 4.2% placebo). TYMLOS (n=690) vs placebo (n=711).

SECONDARY ENDPOINT
NONVERTEBRAL (includes hip fracture)‡

43%

Relative Risk Reduction

43% RRR in nonvertebral fractures (log-rank test *P*=0.049) and 2.0% ARR at 19 months (fracture incidence: 2.7% TYMLOS vs 4.7% placebo). TYMLOS (n=824) vs placebo (n=821).

ARR=absolute risk reduction; ITT=intent-to-treat; RRR=relative risk reduction.

†Modified ITT population, which includes patients who had both pretreatment and posttreatment spine radiographs.
‡Nonvertebral fractures were measured using the ITT population at 19 months (the entire observational period included 18 months of treatment plus 1 month of follow-up). Nonvertebral fractures excluded fractures of the sternum, patella, toes, fingers, skull, and face, and those associated with high trauma.

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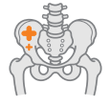
TYMLOS IS PROVEN TO SIGNIFICANTLY INCREASE BMD.

ATOM STUDY DESIGN: Phase 3 randomized, double-blind, placebo-controlled study in men with osteoporosis (N=228) aged 42 to 85 years who were randomized to receive TYMLOS 80 mcg (n=149) or placebo (n=79) subcutaneously once daily for 12 months to assess efficacy and safety of abaloparatide injection.[1,4]

♀ TYMLOS helps women build significant bone mineral density (BMD) gains vs placebo.[1]

♂ TYMLOS quickly and significantly increased BMD in vertebral and nonvertebral bone in men.[1]

Mean change in BMD from the beginning to the end of the study for TYMLOS vs placebo:

	ACTIVE Trial (postmenopausal women)		ATOM Trial (men)
Lumbar Spine	9.2% vs 0.5%*†		8.5% vs 1.2%‡§
Total Hip	3.4% vs –0.1%*†		2.1% vs <0.1%*§
Femoral Neck	2.9% vs –0.4%*†		3.0% vs 0.2%*§

*Secondary endpoints.
†TYMLOS 80 mcg (n=824) vs placebo (n=821).
‡Primary endpoint.
§TYMLOS 80 mcg (n=149) vs placebo (n=79).

The most common adverse reactions (incidence ≥2%) reported with TYMLOS in postmenopausal women with osteoporosis are hypercalciuria (11%), dizziness (10%), nausea (8%), headache (8%), palpitations (5%), fatigue (3%), upper abdominal pain (3%), and vertigo (2%).[1]

The most common adverse reactions (incidence ≥2%) reported with TYMLOS in men with osteoporosis are injection site erythema (13%), dizziness (9%), arthralgia (7%), injection site swelling (7%), injection site pain (6%), contusion (3%), abdominal distention (3%), diarrhea (3%), nausea (3%), abdominal pain (2%), and bone pain (2%).[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia, or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

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EXPERT SUPPORT HELPS YOUR PATIENTS START AND STAY ON TREATMENT.

TYMLOS®

CLINICAL EDUCATOR NETWORK

1-on-1 help for patients

The TYMLOS Clinical Educators are registered nurses who are available to provide training for you and your staff on using the TYMLOS pen. Following prescription, a Clinical Educator can help your patients learn about their injection and train them on how to use the pen.

Your patients can connect to a Clinical Educator

Monday through Friday, 8 AM to 7 PM ET
at 1-855-730-8591

Or register for support at:

https://radius.myregistrationp.com/registration.htm

TYMLOS Patient Savings Card Program: patients with commercial insurance may pay as little as $0 a month; governmental beneficiaries excluded, terms and conditions apply

References: 1. TYMLOS. Prescribing information. Radius Health, Inc. **2.** Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. **3.** Miller PD, Hattersley G, Riis BJ, et al. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis: a randomized clinical trial. *JAMA.* 2016;316(7):722-733. **4.** Czerwinski E, Cardona J, Plebanski R, et al. The efficacy and safety of abaloparatide-SC in men with osteoporosis: a randomized clinical trial. *J Bone Miner Res.* 2022;37(12):2435-2442.

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Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Pregnancy and Lactation: TYMLOS is not indicated for use in females of reproductive potential.

Adverse Reactions:

- The most common adverse reactions (incidence ≥2%) reported with TYMLOS in postmenopausal women with osteoporosis are hypercalciuria (11%), dizziness (10%), nausea (8%), headache (8%), palpitations (5%), fatigue (3%), upper abdominal pain (3%), and vertigo (2%).
- The most common adverse reactions (incidence ≥2%) reported with TYMLOS in men with osteoporosis are injection site erythema (13%), dizziness (9%), arthralgia (7%), injection site swelling (7%), injection site pain (6%), contusion (3%), abdominal distention (3%), diarrhea (3%), nausea (3%), abdominal pain (2%), and bone pain (2%).

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TYMLOS®
(abaloparatide) injection

REDUCE YOUR PATIENT'S RISK OF FRACTURE WITH TYMLOS[1]

- Significantly reduces vertebral and nonvertebral fractures in postmenopausal women with osteoporosis[1]
- Proven to significantly increase bone mineral density (BMD) in men and postmenopausal women with osteoporosis[1]

Rebuild bone with TYMLOS, preserve with follow-on therapy, and help your patients keep doing what they love.[1]

TYMLOS.com/HCP

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RADIUS®