

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TYMLOS safely and effectively. See full prescribing information for TYMLOS.

TYMLOS™ (abaloparatide) injection, for subcutaneous use
Initial U.S. Approval: 2017

WARNING: RISK OF OSTEOSARCOMA
See full prescribing information for complete boxed warning.

- Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma, a malignant bone tumor, in male and female rats. It is unknown whether TYMLOS will cause osteosarcoma in humans. (5.1, 13.1)
- Use of TYMLOS is not recommended in patients at increased risk for osteosarcoma. (5.1)
- Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended. (5.1)

-----INDICATIONS AND USAGE-----
 TYMLOS is a human parathyroid hormone related peptide [PTHrP(1-34)] analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. (1)

-----DOSAGE AND ADMINISTRATION-----
 • Recommended dose is 80 mcg subcutaneously once daily; patients should receive supplemental calcium and vitamin D if dietary intake is inadequate. (2.1)
 • Administer as a subcutaneous injection into periumbilical region of abdomen. (2.2)

- Administer initially where the patient can sit or lie down in case symptoms of orthostatic hypotension occur. (2.2, 5.2)

-----DOSAGE FORMS AND STRENGTHS-----
 Injection: 3120 mcg/1.56 mL (2000 mcg/mL) in a single-patient-use prefilled pen. The prefilled pen delivers 30 daily doses of 80 mcg abaloparatide in 40 mL of sterile, clear, colorless solution. (3)

-----CONTRAINDICATIONS-----
 None (4)

- WARNINGS AND PRECAUTIONS-----
- Orthostatic Hypotension: Instruct patients to sit or lie down if symptoms develop after dose administration. (5.2)
 - Hypercalcemia: Avoid use in patients with pre-existing hypercalcemia and those known to have an underlying hypercalcemic disorder, such as primary hyperparathyroidism. (5.3)
 - Hypercalciuria and Urolithiasis: Monitor urine calcium if preexisting hypercalciuria or active urolithiasis are suspected. (5.4)

-----ADVERSE REACTIONS-----
 The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Radius Health, Inc. at 1-855-672-3487 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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