Tymlos (abaloparatide)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Tymlos
- **Generic name:** Abaloparatide
- **Pharmacological class:** Human parathyroid hormone related peptide analog
- **Strength and Formulation:** 2000mcg/mL; solution for SC injection
- **Manufacturer:** Radius Health
- **How supplied:** Prefilled pen (1.56mL)—1
- **Legal Classification:** Rx

TYMLOS


NDC 70537-001-02
TYMLOS™
(abaloparatide) Injection
80 mcg per dose
3120 mcg/1.56 mL (2000 mcg/mL)
For subcutaneous use
Rx only
Sterile
1 prefilled pen
Needles not included
Each prefilled pen will deliver
30 subcutaneous doses.
Dispense the enclosed
Medication Guide
and Instructions for Use
to each patient.
Radius

Indications

- Postmenopausal women with **osteoporosis** at high risk for fracture

Limitations of Use

- **Cumulative use >2yrs** not recommended

Dosage & Administration

- 80mcg SC once daily into periumbilical region of abdomen; rotate inj sites
- Give supplemental calcium and vitamin D if dietary intake inadequate

Considerations for Special Populations

- **Pregnancy:** Not indicated
- **Nursing mothers:** Not indicated
- **Pediatric:** Not recommended
- **Elderly:** Consider greater sensitivity in geriatric use
- **Renal impairment:** Monitor for adverse reactions

Warnings/Precautions

- Increased baseline risk for **osteosarcoma** (eg, Paget's disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, prior external beam or skeletal implant radiation therapy): **not recommended**

Warnings/Precautions

- Pre-existing hypercalcemia or underlying hypercalcemic disorder (eg, primary hyperparathyroidism): not recommended
- Urolithiasis
- Hypercalciuria

Adverse Reactions

- Hypercalciuria
- Dizziness
- Nausea
- Headache
- Palpitations
- Fatigue
- Upper abdominal pain
- Vertigo
- Orthostatic hypotension
- Hypercalcemia
- Urolithiasis
- Injection site reactions

Mechanism of Action

- Abaloparatide is a **PTHrP(1-34) analog** that acts at the PTH1 receptor and activates cAMP signaling pathway
- Abaloparatide has an anabolic effect on bone, demonstrated by increases in bone mineral density and bone mineral content that correlates with increases in bone strength at vertebral and/or nonvertebral sites

Clinical Studies

- A randomized, double-blind, placebo-controlled clinical trial **(Study 003)** in postmenopausal women with osteoporosis aged 49–86 years
- Patients were randomized to 80mcg Tymlos (n=824) or placebo (n=821) SC once daily for 18 months
- Patients took daily supplemental calcium and vitamin D

Clinical Studies

- **Primary endpoint** was incidence of new vertebral fractures
- Treatment with Tymlos resulted in **significant reduction** in incidence of new vertebral fractures vs. placebo at 18 months (**0.6%** vs. **4.2%**, *P*<0.0001)
- Absolute risk reduction (ARR) was **3.6%** and relative risk reduction (RRR) was **86%** for Tymlos vs. placebo

Clinical Studies

- Treatment with Tymlos resulted in **significant reduction** in incidence of new nonvertebral fractures vs. placebo at 18 months (**2.7%** vs. **4.7%**)
- ARR was **2.0%** and RRR was **43%** (*P*=0.049)

Clinical Studies

- An open-label extended efficacy study **(Study 005)** was started after 1 month of no treatment after the end of Study 003
- Patients were discontinued from Tymlos and placebo, then maintained in their original randomized treatment group to receive alendronate 70mg weekly with calcium and vitamin D for 6 months (n=1,139)

Clinical Studies

- The risk of new vertebral fractures at 25 months in the Tymlos then alendronate group vs. placebo then alendronate group were:
  - **ARR:** 3.9%
  - **RRR:** 87%

Clinical Studies

- The risk for new nonvertebral fractures at 25 months in the Tymlos then alendronate group vs. placebo then alendronate group were:
  - **ARR:** 2.9%
  - **RRR:** 52% (*P*=0.017)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/tymlos/drug/34680/