

## MEDICATION GUIDE

### **TYMLOS® (tim lows') (abaloparatide)**

#### **injection, for subcutaneous use**

#### **What is the most important information I should know about TYMLOS?**

##### **TYMLOS may cause serious side effects including:**

- **Possible bone cancer (osteosarcoma).** During animal drug testing, the medicine in TYMLOS caused some rats to develop a bone cancer called osteosarcoma. It is not known if people who take TYMLOS will have a higher chance of getting osteosarcoma.
  - Tell your healthcare provider right away if you have pain in your bones, pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.

#### **What is TYMLOS?**

TYMLOS is a prescription medicine used to:

- treat osteoporosis in postmenopausal women who are at high risk for bone fracture, or who cannot use another osteoporosis treatment or other osteoporosis treatments did not work well. TYMLOS can decrease the chance of having a fracture of the spine and other bones in postmenopausal women with thinning and weakening bones (osteoporosis)
- increase bone density in men with osteoporosis who are at high risk for bone fracture, or who cannot use another osteoporosis treatment or other osteoporosis treatments did not work well

It is not known if TYMLOS is safe and effective for children 18 years and younger. TYMLOS should not be used in children and young adults whose bones are still growing.

It is not recommended that people use TYMLOS for more than 2 years during their lifetime.

#### **Do not take TYMLOS:**

- if you had an allergic reaction to abaloparatide, or any of the other ingredients in TYMLOS. See the end of this Medication Guide for a complete list of ingredients in TYMLOS.

#### **Before you take TYMLOS, tell your healthcare provider about all of your medical conditions, including if you:**

- have Paget's disease of the bone or other bone disease.
- have or have had cancer in your bones.
- have or have had radiation therapy involving your bones.
- have or have had too much calcium in your blood.
- have or have had an increase in your parathyroid hormone (hyperparathyroidism).
- will have trouble injecting yourself with the TYMLOS pen and do not have someone who can help you.
- are pregnant or plan to become pregnant. TYMLOS is not for pregnant women.
- are breastfeeding or plan to breastfeed. It is not known if TYMLOS passes into your breast milk. You and your healthcare provider should decide if you will take TYMLOS or breastfeed. You should not do both.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist each time you get a new medicine.

## How should I use TYMLOS?

- Read the detailed **Instructions for Use** provided with your medicine.
- Use TYMLOS exactly as your healthcare provider tells you to use it.
- Do not try to inject TYMLOS yourself until you or your caregiver receive training from a healthcare provider on the right way to use the TYMLOS pen.
- You should receive your first several injections of TYMLOS where you can sit or lie down, if necessary, until you know how it affects you.
- Inject TYMLOS 1 time each day into your lower stomach area (abdomen) just under your skin (subcutaneous). Avoid giving your injection within the 2-inch area around your belly button (navel).
- Talk to your healthcare provider about how to change (rotate) your injection site for each injection. Do not give TYMLOS in your veins (intravenously) or deep into your muscles (intramuscularly).
- You can take TYMLOS with or without food or drink.
- Take TYMLOS at about the same time each day.
- If you forget or cannot take TYMLOS at your usual time, take it as soon as you can on that day.
- The TYMLOS pen has enough medicine for 30 days. It is set to give 1 dose of medicine with each injection. Do not take more than 1 injection in the same day.
- Do not transfer the medicine from the TYMLOS pen to a syringe. This can cause you to use the wrong dose of TYMLOS. If you do not have pen needles to use with your TYMLOS pen, talk with your healthcare provider.
- Do not share your TYMLOS pen or pen needles with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
- TYMLOS should look clear and colorless. Do not use TYMLOS if it has particles in it, or if it is cloudy or colored.
- Your healthcare provider may do blood and urine tests during your treatment with TYMLOS.
- Your healthcare provider may ask you to have a bone mineral density test after your treatment with TYMLOS.
- If you take more TYMLOS than prescribed you may have symptoms such as muscle weakness, low energy, headache, nausea, dizziness (especially when getting up after sitting for a while), and a faster heartbeat. Stop taking TYMLOS and call your healthcare provider right away.
- You should not use TYMLOS for more than 2 years over your lifetime.
- If your healthcare provider recommends calcium and vitamin D supplements, you can take them while using TYMLOS.

**What are the possible side effects of TYMLOS? TYMLOS may cause serious side effects including:**

- See “**What is the most important information I should know about TYMLOS?**”
- **Decrease in blood pressure when you change positions.** Some people may feel dizzy, have a faster heartbeat, or feel lightheaded soon after the TYMLOS injection is given. These symptoms generally go away within a few hours. Take your injections of TYMLOS in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, stop taking TYMLOS and call your healthcare provider.
- **Increased blood calcium (hypercalcemia).** TYMLOS can cause some people to have a higher blood calcium level than normal. Your healthcare provider may check your blood calcium before you start and during your treatment with TYMLOS. Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- **Increased urine calcium (hypercalciuria).** TYMLOS can cause some people to have higher levels of calcium in their urine than normal. Increased calcium may also cause you to develop kidney stones (urolithiasis) in your kidneys, bladder, or urinary tract. Tell your healthcare provider right away if you get any symptoms of kidney stones which may include pain in your lower back or lower stomach area, pain when you urinate, or blood in your urine.

**The most common side effects of TYMLOS in women with postmenopausal osteoporosis include:**

- dizziness
- nausea
- headache
- fast heartbeat
- feeling tired (fatigue)
- upper stomach pain
- spinning feeling (vertigo)

**The most common side effects of TYMLOS in men with osteoporosis include:**

- redness at injection site
- dizziness
- joint pain
- swelling at injection site
- pain at injection site
- bruising
- abdominal bloating
- diarrhea
- nausea
- abdominal pain
- bone pain

These are not all the possible side effects of TYMLOS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store TYMLOS?**

- **Before first use**, store TYMLOS pens in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **After first use**, store your TYMLOS pen for up to 30 days at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not freeze** the TYMLOS pen or expose it to heat.
- Do not use TYMLOS after the expiration date printed on the pen and packaging.
- Throw away the TYMLOS pen after 30 days even if some medicine is left in the pen (see “**Instructions for Use**”). **Keep TYMLOS and all medicines out of the reach of children.**

**General information about the safe and effective use of TYMLOS.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TYMLOS for a condition for which it was not prescribed. Do not give TYMLOS to other people, even if they have the same condition you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TYMLOS that is written for health professionals.

**What are the ingredients in TYMLOS?**

**Active ingredient:** abaloparatide

**Inactive ingredients:** acetic acid, phenol, sodium acetate trihydrate, and water for injection.

**RADIUS®**

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For more information about TYMLOS, visit our website at [www.TYMLOS.com](http://www.TYMLOS.com) or call Radius Health, Inc., at 1-855-672-3487.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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