

IMPORTANT SAFETY INFORMATION

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, 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.

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 too much of an enzyme called alkaline phosphatase 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.

What are the possible side effects of TYMLOS?

TYMLOS can cause serious side effects including:

- 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 include:

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

- vertigo

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](tel:1-800-FDA-1088).

- If you take more TYMLOS than prescribed you may experience 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.

What is TYMLOS?

TYMLOS is a prescription medicine used to:

- decrease the chance of having a fracture of the spine and other bones in postmenopausal women with thinning and weakening bones (osteoporosis).
- treat osteoporosis in postmenopausal women who are at high risk for bone fracture.

It is not known if TYMLOS is safe and effective for children 18 years and younger.

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

TYMLOS should not be used in children and young adults whose bones are still growing.