

# DISCOVER

# **TYMLOS**<sup>®</sup>

(abaloparatide) injection

## INDICATIONS

### 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 and young adults 18 years and younger. TYMLOS should not be used in children and young adults whose bones are still growing.

Please read Important Safety Information on pages 10-11.

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## WHEN IS IT TIME FOR TYMLOS?

Osteoporosis is a bone disease that weakens bones and makes them fragile. If your bones are weak, you are at risk for fracture.

If you are at high risk for fracture, have had an intolerance to other osteoporosis treatments, or previous osteoporosis treatments have failed to stop bone loss, it is time to rebuild bones with the help of TYMLOS.



### SELECTED 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.

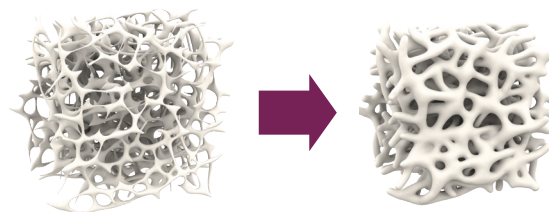
- Tell your healthcare provider right away if you have pain in your bones, pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.

## HOW TYMLOS WORKS

### TYMLOS rebuilds bone

TYMLOS works differently than some other osteoporosis treatments. In addition to slowing down bone loss, TYMLOS helps activate your bone-building cells to rebuild the bone you've lost.

Rebuilding bone may help reduce your risk for a future fracture



**BONE WITH OSTEOPOROSIS**


**REBUILDING BONE**


*Diagram is illustrating the bone-building process.  
Not intended to imply efficacy.*


# TYMLOS FOR POSTMENOPAUSAL WOMEN

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A clinical study looked at safety and how effective TYMLOS was at treating osteoporosis by reducing the risk for fracture in postmenopausal women.

 The study included more than 2,460 postmenopausal women worldwide

 Women taking TYMLOS were compared with women taking a placebo (an injection that did not contain any medicine)

 TYMLOS was taken for 18 months

After completing treatment with TYMLOS, your doctor may recommend transitioning to a medication that may help maintain reduced risk for fracture in postmenopausal women with osteoporosis.

## MOST COMMON SIDE EFFECTS OF TYMLOS REPORTED IN TRIALS WITH POSTMENOPAUSAL WOMEN

 DIZZINESS

 FEELING TIRED (FATIGUE)

 NAUSEA

 UPPER STOMACH PAIN

 HEADACHE

 SPINNING FEELING (VERTIGO)

 FAST HEARTBEAT

## AT 18 MONTHS IN A CLINICAL TRIAL



TYMLOS was proven to reduce the risk of fracture in the spine by

**86%**

0.6% of women taking TYMLOS had a spinal fracture vs 4.2% of women taking placebo.



TYMLOS was proven to reduce the risk of nonspinal fracture by

**43%**

2.7% of women taking TYMLOS had a nonspinal fracture vs 4.7% of women taking placebo.



Increased BMD at the spine, hip, and neck of the femur was demonstrated in women taking TYMLOS compared to those taking placebo

Mean change in BMD from the beginning to the end of the study for TYMLOS vs placebo—lumbar spine: 9.2% vs 0.5%; total hip: 3.4% vs -0.1%; femoral neck: 2.9% vs -0.4%.

BMD=bone mineral density, a measure of the amount of mineral in your bones.

A clinical study looked at safety and how effective TYMLOS was at increasing BMD in men with osteoporosis.



The study included more than 228 men worldwide



Men taking TYMLOS were compared with men taking a placebo (an injection that did not contain any medicine)



TYMLOS was taken for 12 months

## MOST COMMON SIDE EFFECTS OF TYMLOS REPORTED IN TRIALS WITH MEN



REDNESS, SWELLING  
OR PAIN AT  
INJECTION SITE



ABDOMINAL  
BLOATING  
OR PAIN



DIZZINESS



DIARRHEA



JOINT PAIN



NAUSEA



BRUISING



BONE PAIN

## IN A CLINICAL TRIAL



**TYMLOS significantly improved BMD**

After 12 months of TYMLOS, BMD was increased at the spine, hip, and neck of the femur compared to men taking placebo.

Mean change in BMD from the beginning to the end of the study for TYMLOS vs placebo—lumbar spine: 8.5% vs 1.2%; total hip: 2.1% vs <0.1%; femoral neck: 3.0% vs 0.2%.



**With TYMLOS, improvements in BMD were observed as early as 3 months**

After 3 months of treatment with TYMLOS, BMD was significantly increased at the spine, hip, and neck of the femur compared to men taking placebo.

Mean change in BMD from the beginning to the end of the study for TYMLOS vs placebo—lumbar spine: 3.8% vs 1.1%; total hip: 1.1% vs 0.2%; femoral neck: 1.4% vs 0.2%.

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# TREATMENT WITH TYMLOS

**TYMLOS**<sup>®</sup>  
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## The TYMLOS pen is thoughtfully designed.

TYMLOS is a daily injection for both men and postmenopausal women with osteoporosis.



### SMALL NEEDLE (5 to 8 mm)

The pen needle is about the length of an eyelash.

### 30-DAY SUPPLY

Each pen has 30 days of medicine.

### WITH OR WITHOUT FOOD

You can take TYMLOS with or without food or drink. Take TYMLOS at about the same time each day.

### GOES WHERE YOU GO

For how to properly store your pen, see the blue box to the right.

*Pen shown not actual size.*

## HOW TO PROPERLY STORE YOUR PEN



**Before first use**, store your TYMLOS in the refrigerator, between 36 °F and 46 °F (2 °C and 8 °C).



**After first use**, store TYMLOS for up to 30 days at room temperature, between 68 °F and 77 °F (20 °C and 25 °C).



**Do not store pens with the needle attached**, and always keep the pen cap on when not in use.



**Do not freeze the TYMLOS pen** or expose it to heat.

Keep out of the reach of children and throw the pen away 30 days after first use in an appropriate container.

For more information on proper disposal, visit [TYMLOS.com/instructions-for-use](https://www.tymlos.com/instructions-for-use)



Learn how to inject TYMLOS at [TYMLOS.com/instructions](https://www.tymlos.com/instructions)

## SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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

### Do not take TYMLOS:

- if you had an allergic reaction to abaloparatide or any of the other ingredients in TYMLOS. The inactive ingredients in TYMLOS are phenol, sodium acetate trihydrate, acetic acid, and water for injection.

## INDICATIONS

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## IMPORTANT SAFETY INFORMATION

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

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- 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.

#### Do not take TYMLOS:

- if you had an allergic reaction to abaloparatide or any of the other ingredients in TYMLOS. The inactive ingredients in TYMLOS are phenol, sodium acetate trihydrate, acetic acid, and water for injection.

#### 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 any of the following: cancer in your bones; radiation therapy involving your bones; too much calcium in your blood; or 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, because TYMLOS is not for pregnant women, or if you are breastfeeding or plan to breastfeed. It is not known if TYMLOS passes into your breast milk; you should not take TYMLOS and breastfeed.

#### 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 injection 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, and 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, and 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 the FDA at 1-800-FDA-1088.

## How should I use TYMLOS?

- Read the complete **Instructions for Use** provided with your medicine.
- 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.
- You should not use TYMLOS for more than 2 years over your lifetime.

**Please read the enclosed copy of the full Prescribing Information, including Medication Guide.**

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# CLINICAL EDUCATOR NETWORK

1-on-1 help for patients

**Your dedicated Clinical Educator  
is here for you**

While taking TYMLOS, you will have access to a dedicated Clinical Educator. They'll start with 1-on-1 injection training and be there for you throughout the duration of your treatment to offer support and answers about taking TYMLOS.



GET CONNECTED TO A  
CLINICAL EDUCATOR  
BY CALLING

**1-855-730-8591**

MONDAY THROUGH FRIDAY, 8 AM-7 PM ET

Enroll at [TYMLOSsignup.com](https://TYMLOSsignup.com)

**Learn more at [TYMLOS.com](https://TYMLOS.com)**

Please read Important Safety Information on pages 10-11 and enclosed full Prescribing Information, including Medication Guide.

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