

## YOUR TREATMENT GUIDE

 **Osenvelt**<sup>®</sup>  
(denosumab-bmwo)

# HELP ALONG THE WAY IN YOUR FIGHT FOR STRONGER BONES

**Get to know OSENVELT, an FDA-approved biosimilar to Xgeva<sup>®</sup> (denosumab)**

**OSENVELT is a prescription medicine used to:**

- Help prevent bone complications in patients with multiple myeloma and in patients whose cancer from solid tumors has spread to the bones.
- Treat adults and adolescents (whose bones have stopped growing) with giant cell tumor of bone that cannot be removed with surgery, or when surgery could cause severe complications.
- Treat high blood calcium caused by cancer (hypercalcemia of malignancy) that has not improved after treatment with bisphosphonates.

## IMPORTANT SAFETY INFORMATION

If you receive OSENVELT, you should not receive other denosumab products at the same time.

FDA, Food and Drug Administration.

## What is OSENVELT?

### OSENVELT is a prescription biosimilar

OSENVELT is a biosimilar of Xgeva® (denosumab). Biosimilar means that:



- A biologic product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product
- There are no clinically meaningful differences in how it works or in how safe it is compared to the reference product

A biosimilar is typically more affordable than the reference product.

Since OSENVELT is a biosimilar of Xgeva, it can be used instead of Xgeva.



### Like Xgeva, OSENVELT helps protect bones from damage caused by certain types of cancer

Certain cancers can affect the way your bones stay strong by speeding up bone breakdown. This can increase your risk of serious bone problems.

OSENVELT works by blocking a natural protein in your body called RANKL. This protein signals cells that break down bones. By blocking RANKL, OSENVELT helps slow bone breakdown.

OSENVELT is **not** a cancer treatment.

### IMPORTANT SAFETY INFORMATION continued

#### OSENVELT can cause serious side effects including:

**Serious allergic reactions.** Serious allergic reactions have occurred with denosumab products. Call your doctor or seek emergency care immediately if you experience symptoms such as low blood pressure (hypotension), rash, difficulty breathing, itching, throat tightness, hives, or swelling of your face, lips, or tongue.

### Why did my doctor prescribe OSENVELT?

Your doctor prescribed OSENVELT to help prevent bone weakening and reduce the risk of fractures.

#### OSENVELT can be used to prevent serious bone problems\* in:



People with  
**Multiple Myeloma**



People with  
**Bone Metastases**  
from solid tumors



Adults and skeletally mature adolescents with  
**Giant Cell Tumor of Bone**  
that is unresectable or where surgical resection is likely to result in severe morbidity



People receiving treatment for  
**Hypercalcemia**  
of malignancy refractory to bisphosphonate therapy

\*Serious bone problems include:

- Broken bones
- Problems with your bones that require surgery
- Need for radiation treatment to the bone
- Pressure on the spinal cord (compression)

### IMPORTANT SAFETY INFORMATION continued

**Low blood calcium (Hypocalcemia).** OSENVELT can lower your blood calcium levels, which can become severe or even life-threatening. Your doctor will check your calcium levels before and during treatment, especially in the first few weeks. You may need to take calcium, magnesium, and vitamin D supplements as instructed by your doctor. Your risk may be higher if you have kidney problems or take other medicines that lower blood calcium. Call your doctor immediately if you experience symptoms of low blood calcium, such as muscle spasms or cramps, numbness or tingling in fingers, toes, or around your mouth, twitching or stiffness.

## How OSENVELT can help

The medicine in OSENVELT, denosumab-bmwo, has been shown to be as effective as denosumab, the medicine in Xgeva®

In people with:

- metastatic breast cancer or castration-resistant prostate cancer, denosumab extended the time to first onset of bone complications compared with zoledronic acid
- bone metastases due to solid tumors or multiple myeloma, denosumab was as least as good as zoledronic acid in prolonging the time to the onset of bone complications

In clinical studies of Xgeva in people whose cancer had spread to their bones, denosumab—the active ingredient in both Xgeva and OSENVELT—was compared to another medicine called zoledronic acid, which is also used to treat bone complications from cancer.



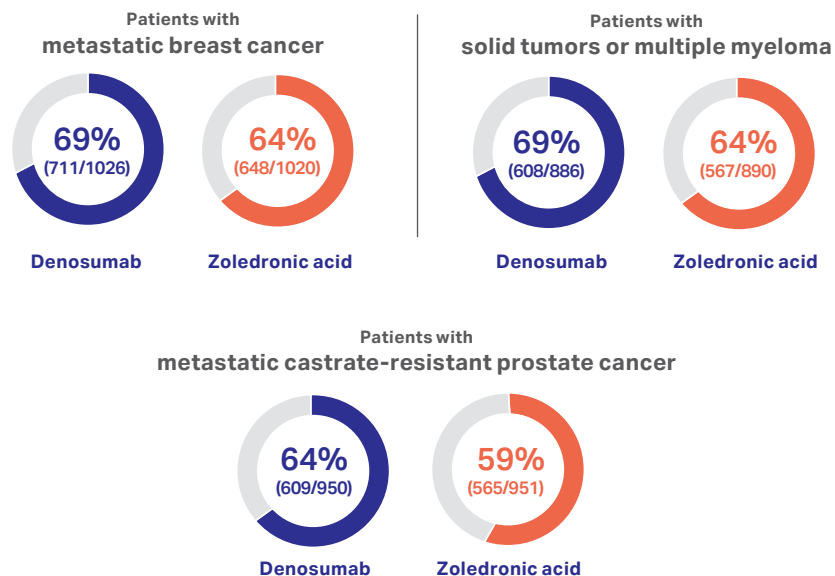
Models are used for illustrative purposes only. Not actual patients.

### IMPORTANT SAFETY INFORMATION continued

**Severe jawbone problems (osteonecrosis).** Severe jaw bone problems may happen when you take OSENVELT. Your doctor should examine your mouth before starting treatment and may advise seeing a dentist. Practice good oral care and consult your doctor or dentist if needed.

**Unusual thigh bone fractures.** Symptoms include new or unusual pain in your hip, groin, or thigh.

### Patients who had no serious bone complications



Denosumab protected patients from serious bone complications—over 64% of patients across all uses had no serious bone complications.



OSENVELT is approved for other uses similar to Xgeva, including some that weren't directly studied. The FDA looks at a wide variety of tests and data to determine that a drug is biosimilar to a reference product, including clinical trials, blood and immune system evaluations, and chemical analyses. OSENVELT passed these tests and is an FDA-approved biosimilar to Xgeva.

# Side effects of OSENVELT

## Common side effects of OSENVELT:

### In people with bone metastases from solid tumors:

- Tiredness/weakness
- Low phosphate levels in the blood
- Nausea

### In people with multiple myeloma:

- Diarrhea
- Nausea
- Low number of red blood cells
- Low number of blood platelets
- Back pain
- Low calcium levels
- Swelling of the lower legs or hands
- Upper respiratory tract infection
- Rash
- Headache

The most common serious side effect was pneumonia.

### In people with giant cell tumor of bone:

- Joint pain
- Headache
- Nausea
- Back pain
- Fatigue
- Pain in legs, arms, or hands

Please speak to your doctor for medical advice about side effects before starting OSENVELT.

### In people getting treatment for hypercalcemia of malignancy:

- Nausea
- Difficulty breathing
- Decreased appetite
- Headache
- Swelling in the lower legs or hands
- Vomiting
- Low number of red blood cells
- Constipation
- Diarrhea

These are not all the possible side effects of OSENVELT. Other side effects have been reported. It is important to be aware and look for signs and symptoms.

You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to  
Celltrion USA, Inc. at 1-800-560-9414.



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**Unusual thigh bone fractures.** Symptoms include new or unusual pain in your hip, groin, or thigh.

**High Blood Calcium After Stopping Treatment.** If you have giant cell tumor of bone or are still growing, stopping OSENVELT can lead to high calcium levels in your blood (hypercalcemia). This condition can become severe, require hospitalization, and affect your kidneys. Your doctor will monitor your calcium levels after stopping treatment. Call your doctor right away if you notice symptoms of high blood calcium, such as nausea or vomiting, increased thirst or urination, confusion or tiredness, muscle weakness or pain. Follow your doctor's instructions carefully, and keep all scheduled appointments for calcium monitoring.

**Multiple Spine Fractures After Stopping OSENVELT.** After stopping treatment with OSENVELT, some patients have experienced multiple spine fractures. Your risk is higher if you have osteoporosis, previous fractures, or other risk factors. Your doctor will assess your individual fracture risk when stopping OSENVELT.

**Risk to Unborn Babies.** OSENVELT may harm your unborn baby if you take it while pregnant or within 5 months before becoming pregnant. Animal studies have shown serious harm, including pregnancy loss, birth defects, abnormal bone growth, missing lymph nodes, and slow growth after birth. Your doctor will check if you are pregnant before starting OSENVELT. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment.

**Do not take OSENVELT if** you have low blood calcium, are pregnant or planning pregnancy, or if you're allergic to denosumab or any ingredients in OSENVELT.

### Before taking OSENVELT, tell your doctor if you:

- take other denosumab products
- have low blood calcium
- cannot take daily calcium and vitamin D supplements
- take medicines that can lower blood calcium
- plan dental surgery or tooth removal
- are pregnant, planning pregnancy, or breastfeeding. OSENVELT may harm an unborn baby; a pregnancy test is required before treatment; use effective birth control during treatment and for 5 months after your last dose; inform your doctor immediately if pregnancy occurs. It is unknown if OSENVELT passes into breast milk; do not breastfeed during treatment.

**Tell your doctor of all medicines, vitamins, and herbal supplements you take.** Keep an updated list to share with healthcare providers.

### The most common side effects of OSENVELT are:

**For patients with Bone Metastasis from Solid Tumors:** fatigue or weakness, low phosphate levels, and nausea.

**For patients with Multiple Myeloma:** diarrhea, low phosphate, nausea, fatigue, low calcium, shortness of breath, and anemia.

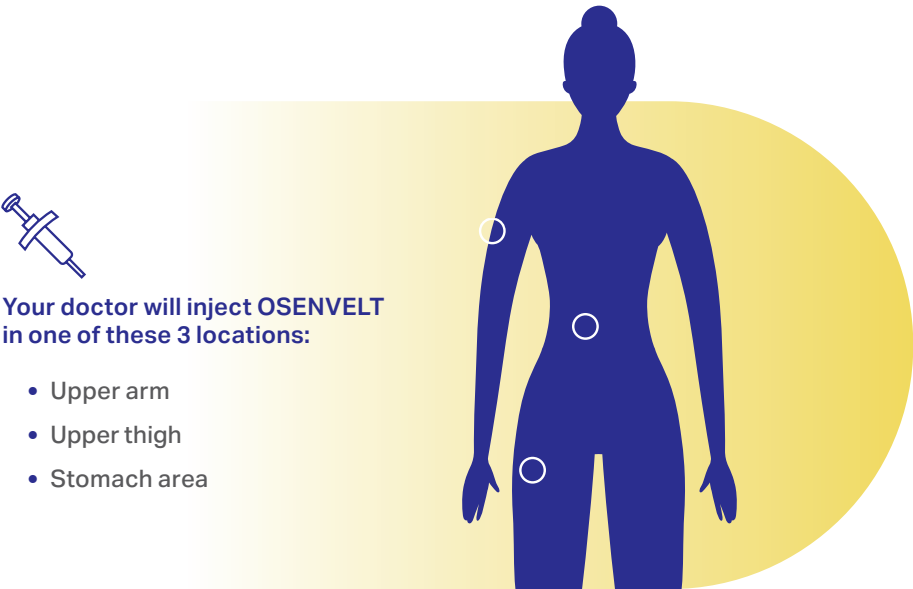
**For patients with Giant Cell Tumor of Bone:** joint pain, headache, nausea, back pain, fatigue, and pain in arms or legs.

**For patients with Hypercalcemia of Malignancy:** nausea, trouble breathing, decreased appetite, and headache.

# What to expect during treatment with OSENVELT

## Administration

OSENVELT is given as a shot under the skin by your healthcare provider. It does not require an infusion.



Your doctor will inject OSENVELT in one of these 3 locations:

- Upper arm
- Upper thigh
- Stomach area

Your doctor may test your blood calcium level before you start OSENVELT and while you are taking OSENVELT.

### Kidney function

You can take OSENVELT even with lower kidney function. If your kidney function is lower than normal, you ARE at increased risk for low blood calcium levels. Consult your doctor on how to manage your individual risk.

## IMPORTANT SAFETY INFORMATION continued

**High Blood Calcium After Stopping Treatment.** If you have giant cell tumor of bone or are still growing, stopping OSENVELT can lead to high calcium levels in your blood (hypercalcemia). This condition can become severe, require hospitalization, and affect your kidneys. Your doctor will monitor your calcium levels after stopping treatment. Call your doctor right away if you notice symptoms of high blood calcium, such as nausea or vomiting, increased thirst or urination, confusion or tiredness, muscle weakness or pain. Follow your doctor's instructions carefully, and keep all scheduled appointments for calcium monitoring.

## Dosing

If you were prescribed OSENVELT for:	Your doctor will administer OSENVELT every:
Multiple myeloma and metastases from solid tumors	4 weeks
Giant cell tumor of bone	4 weeks <ul style="list-style-type: none"><li>• With extra doses on days 8 and 15 of the first month of treatment</li></ul>
Cancer-related hypercalcemia	4 weeks <ul style="list-style-type: none"><li>• With extra doses on days 8 and 15 of the first month of treatment</li></ul>

## IMPORTANT SAFETY INFORMATION continued

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**Risk to Unborn Babies.** OSENVELT may harm your unborn baby if you take it while pregnant or within 5 months before becoming pregnant. Animal studies have shown serious harm, including pregnancy loss, birth defects, abnormal bone growth, missing lymph nodes, and slow growth after birth. Your doctor will check if you are pregnant before starting OSENVELT. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment.

## Starting OSENVELT

### Before you start treatment

Speak to your doctor about your medical history, especially if you are or may become pregnant, or if you have a history of kidney problems.

Your doctor may want to give you some tests to make sure OSENVELT is right for you. These tests include:



#### Calcium level test

Your doctor will give you a test to measure the amount of calcium in your blood. If the level is too low, you will probably need to take medicine to bring your calcium level up to normal.



#### Pregnancy test

If you can become pregnant, your doctor will test to make sure you are not pregnant before starting OSENVELT. Women should use birth control the entire time they are taking OSENVELT and for 5 months after their last dose of OSENVELT.

Make sure you tell your doctor if you are pregnant, are planning to get pregnant, think you may be pregnant, or are breastfeeding.



#### Dental evaluation

Your doctor will likely want you to have a dental exam before starting OSENVELT.

Tell your doctor about any tooth pain you have or dental work you are planning to have. In clinical studies, some patients taking denosumab experienced jawbone deterioration, a condition called osteonecrosis of the jaw.

Let your dentist know that you are taking OSENVELT. Make sure you visit your dentist as your doctor recommends.



### IMPORTANT SAFETY INFORMATION continued

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### IMPORTANT SAFETY INFORMATION continued

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#### **Tell your doctor of all medicines, vitamins, and herbal supplements you take.**

Keep an updated list to share with healthcare providers.

## Getting the most out of OSENVELT

### At your appointment



- Wear loose, comfortable clothing
- Schedule your next appointments in advance as instructed by your doctor

### Things to do every day



- Maintain good oral hygiene:
  - Brush twice daily
  - Use a fluoride toothpaste
  - Brush for 2 minutes each time you brush
  - Floss your teeth every day
  - Eat a healthy diet and limit sugar
  - Visit your dentist regularly



### IMPORTANT SAFETY INFORMATION continued

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**For patients with Multiple Myeloma:** diarrhea, low phosphate, nausea, fatigue, low calcium, shortness of breath, and anemia.

## Celltrion support programs

### These programs help you get better access to OSENVELT



Help verify your insurance coverage for OSENVELT, determine your plan-specific requirements, and understand your available benefits



Connect with Celltrion CARES® for co-pay assistance with your commercial insurance



### IMPORTANT SAFETY INFORMATION continued

**For patients with Giant Cell Tumor of Bone:** joint pain, headache, nausea, back pain, fatigue, and pain in arms or legs.

**For patients with Hypercalcemia of Malignancy:** nausea, trouble breathing, decreased appetite, and headache.





# HELP ALONG THE WAY

Please see Important Safety Information throughout and on pages 8-9.  
Full Prescribing Information is available [here](#).

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OSENVELT is a registered trademark of Celltrion, Inc.,  
used under license. Celltrion CARES is a registered  
trademark of Celltrion, Inc., used under license.  
Celltrion CONNECT is a registered trademark of Celltrion  
Holdings Co., Ltd., used under license.

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