

YOUR JOURNEY TO HELPING BUILD NEW BONE

A guide to managing your
postmenopausal osteoporosis



INDICATION

EVENTITY® is a prescription medicine used to treat osteoporosis in women after menopause who are at high risk of fracture, or cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about EVENTITY®?

EVENTITY® can cause serious side effects, including increased risk of having a heart attack, stroke, or death from a cardiovascular (heart or blood vessel) problem. Call your healthcare provider or get emergency help right away if you have any of these symptoms: symptoms of **heart attack**, which may include: chest pain or pressure; shortness of breath; feeling light-headed or dizzy; or symptoms of **stroke**, which may include: headache; numbness or weakness in face, arm, or legs; difficulty talking; changes in vision or loss of balance. Before you receive EVENTITY®, tell your healthcare provider if you have had a heart attack or stroke, especially if it has happened in the past year.

Please see additional Important Safety Information on page 11.

 **EVENTITY®**
(romosozumab-aqqg)
injection 105 mg/1.17 mL

Take your first step toward helping build new bone

This guide is designed to help you understand a little more about managing osteoporosis after menopause, so you and your healthcare provider can create a plan that fits with your personal goals.



Patient instructions: Review this kit, and then discuss with your healthcare provider as you work together to map your treatment journey.



Healthcare provider instructions: Start by reviewing the patient's answers to the questions on the inserted pages. Then work with the patient to fill out the fields and plot the T-score chart on page 4.

After you break a bone due to osteoporosis, your risk remains high for another fracture

After an osteoporosis-related fracture,

YOU ARE 5x
more likely to suffer another
FRACTURE IN 1 YEAR¹



Your risk remains elevated over time

Potential impact of broken bones



A move to a nursing home or **long-term care** facility²



Complications
during hospitalization
(due to hip fracture)³



Potential burden of broken bones
on you, your family,
and your finances⁴⁻⁶



A fracture can be a life-changing event.^{3,7} Don't waste precious time. Help reduce your risk of a potentially life-altering fracture by talking to your doctor about starting treatment for your osteoporosis.

Start making your plan

Are you at risk for breaking another bone? Your chances are higher if you've had one osteoporotic fracture. And the possibility increases even more if you have any one of these additional risk factors⁸⁻¹⁰:

- ☐ T-score less than -2.5
- ☐ Cigarette smoking
- ☐ Age 65 or older
- ☐ Rheumatoid arthritis
- ☐ Low body weight
- ☐ Long-term corticosteroid use (such as prednisone)
- ☐ Parent suffered hip fracture
- ☐ Diabetes



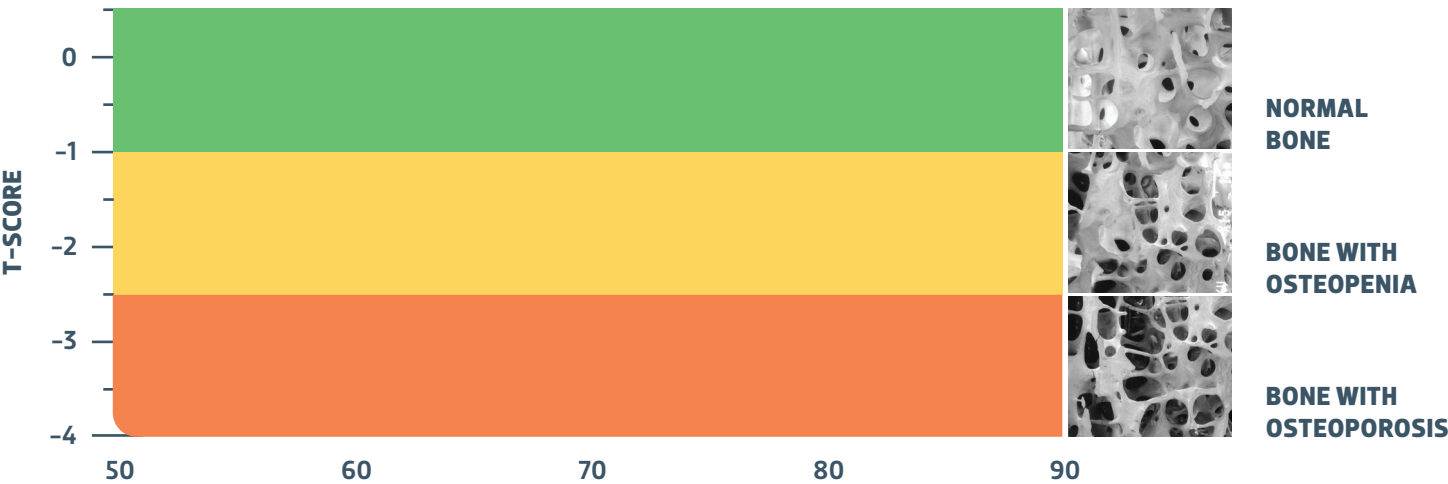
Healthcare provider instructions: Fill out the following fields and plot chart. Use the lowest T-score identified by the DXA scan.¹¹

T-score is a measure of bone density, which helps determine the severity of osteoporosis and your risk for fracture.¹⁰ Let's look at your T-score.

T-score site: _____

Prior T-score: _____ Date: _____

Current T-score: _____ Date: _____



Bone images courtesy of David W. Dempster, PhD, 2000. Reproduced with permission.



Based on my clinical judgment, your risk factors, your T-score, and prior osteoporosis-related fracture, I recommend that you:

Start prescription treatment

- ☐ Review details and side effects



Create a long-term plan

- ☐ Schedule follow-ups and a reevaluation after 12 months

Understanding your prescription treatment options to manage osteoporosis after menopause^{9,12-22}

This information is provided to help show you that osteoporosis treatments work differently. It is not meant to show you that one is better than another. You and your healthcare provider will decide what treatment is right for you.

	EVENTITY^{®9}	Other Anabolic Medications^{17,21,22}	Antiresorptive Medications^{14,19,20,22}
How does it work?	Builds bone and slows bone loss to a lesser extent Increases the level of activity of bone-building cells + Reduces bone-removing cells	Builds bone Increases the level of activity of bone-building cells	Slows bone loss Helps stop bone-removing cells, leading to less bone loss
How do I take it?	Injection by your healthcare professional	Self-administered injection	Oral tablet or oral solution or Intravenous infusion or subcutaneous injection (given by healthcare provider)
How often do I take it?	Once monthly for 12 months	Once daily for up to 2 years	Once daily, once weekly, once monthly, once every 3 months, once every 6 months, or once a year



After you have completed treatment with **EVENTITY[®]**, help keep the new bone you've built by making an antiresorptive therapy the next step in your treatment plan.⁹

Please see Important Safety Information on page 11.


EVENTITY[®]
 (romosozumab-aqqg)
 injection 105 mg/1.17 mL

For women with osteoporosis after menopause at high risk for fracture

Get to know EVENITY® (romosozumab-aqqg)

Rapidly reduce spine fracture risk in 12 months with EVENITY®⁹

At 12 months,

**EVENITY® significantly reduced
the risk of spine fractures in women by 73%**

The study followed 7180 women with postmenopausal osteoporosis receiving EVENITY® or placebo (a treatment without medicine) for 12 months. Women receiving EVENITY® had fewer new spine fractures (0.5%) than women receiving placebo (1.8%) at 12 months. Reductions in fractures other than spine were not significant at 12 months.



In the same clinical study, women on EVENITY® rapidly increased the bone mineral density of their lower spine, hip, and femoral neck (thighbone) at 12 months.

Important Safety Information

Do not take EVENITY® if you: have low blood calcium; or are allergic to romosozumab or any of the ingredients in EVENITY®.

Please see additional Important Safety Information on page 11.

Help build new bone in 12 months with EVENITY®

See the bone-building effects of EVENITY®

With EVENITY®

Without EVENITY®

Pelvic bone samples taken at 12 months^{*,9,23}



*For illustrative purposes only. Bone samples were taken from 2 different women from a substudy consisting of 139 women with postmenopausal osteoporosis. Images selected are from women who were close to the average of each group.

The first and only osteoporosis treatment that works in 2 ways^{9,12-21,24}



EVENITY® increases bone formation and, to a lesser extent, decreases bone loss.

Image is for explanation only and is not meant to imply benefits.

Important Safety Information

EVENITY® may cause serious side effects. Possible serious side effects include serious allergic reactions, low blood calcium, severe jaw bone problems, and unusual thigh bone fractures.

Please see additional Important Safety Information on page 11.

 **EVENITY®**
(romosozumab-aqqg)
injection 105 mg/1.17 mL

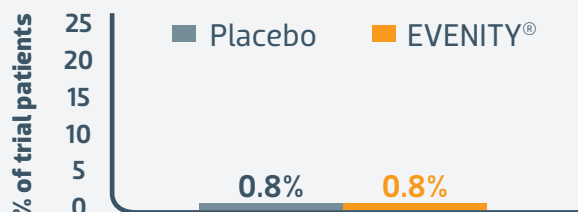
What are the possible side effects of EVENITY® (romosozumab-aqqg)?

Before taking EVENITY®, tell your healthcare provider if you have had a heart attack or stroke, especially if it has happened in the past year.

EVENITY® can cause serious side effects, including⁹:

- Increased risk of having a heart attack, stroke, or death from a cardiovascular (heart or blood vessel) problem
- Low calcium levels in your blood (hypocalcemia)
- Severe jawbone problems (osteonecrosis)
- Serious allergic reactions
- Unusual thighbone fractures

The following are the percentage of women in 2 clinical trials who experienced either a heart attack, stroke, or death due to a cardiovascular problem⁸



- Study 1 followed 7180 women with postmenopausal osteoporosis receiving EVENITY® or placebo for 12 months
- This study showed a hazard ratio of 1.03 for EVENITY® compared to placebo
- 30 women out of 3581 (0.8%) in the EVENITY® arm experienced a major adverse cardiac event



- Study 2 followed 4093 women with postmenopausal osteoporosis receiving EVENITY® or alendronate for 12 months
- This study showed a hazard ratio of 1.87 for EVENITY® compared to alendronate
- 41 women out of 2040 (2.0%) in the EVENITY® arm experienced a major adverse cardiac event

The most common side effects seen with EVENITY® were joint pain and headache.⁹

In Study 1, the most common side effects occurring ≥ 5% of the time or more were:

	EVENITY®	Placebo
Joint pain	13.1%	12.1%
Headache	6.6%	5.8%

Talk to your healthcare provider about the risks vs benefits of treatment.

For a woman with postmenopausal osteoporosis, a fracture can happen from even a minor event, like a fall from standing height. For a woman without osteoporosis, that same fall may not result in a broken bone.

That's why it's important to discuss the risks of not getting treated with EVENITY® and the risks of possible side effects. You and your healthcare provider can decide what's right for you.

These are not all of the side effects of EVENITY®.

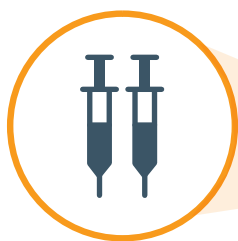
Please see additional Important Safety Information on page 11.

Help build new bone with 12 doses

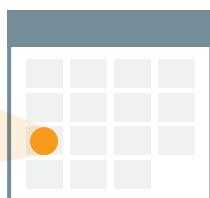
EVENTITY® is the only bone-building treatment given as 12 monthly doses.^{9,17,21}

Each **EVENTITY®** dose consists of 2 shots given every month by your doctor or healthcare provider.⁹

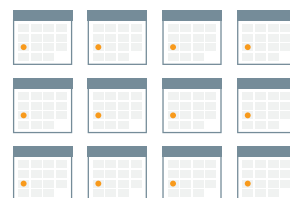
You should take calcium and vitamin D as your doctor tells you to while you receive **EVENTITY®**. If you miss an appointment, contact your doctor as soon as possible to reschedule.⁹



1 DOSE
(2 SHOTS)



GIVEN **MONTHLY**
DURING THE SAME VISIT



FOR
12 MONTHS



KEEP the NEW BONE you've built

Since osteoporosis is a chronic disease, your healthcare provider may transition you to a follow-up treatment after you have completed 12 months of **EVENTITY®** to help maintain and **protect the bone you've built.**^{8,9}

Stay supported throughout your journey and check out **BONE MATTERS®**, your comprehensive support program to provide helpful information. **Bone Matters®** is with you from the start.

**BONE
MATTERS®**

Bone Matters® offers exclusive access to lifestyle tips, educational information, and more to help you achieve your bone health goals while on **EVENTITY®**.



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Please see Important Safety Information on page 11.

Common questions about EVENITY® (romosozumab-aqqg)



How does postmenopausal osteoporosis impact my risk of fracture?

Osteoporotic bones can break from even everyday activities. If you've already had an osteoporotic fracture, your chances of breaking another bone increase significantly.^{1,25}

But there's something you can do to help reduce that risk—start on a bone-building treatment, like EVENITY®, to help build new bones in 12 doses.⁹



What happens if I miss a dose?

It's important to stay on track with your treatment. If you miss an appointment, contact your healthcare provider as soon as possible to reschedule.⁹



How does EVENITY® work?

EVENITY® works in 2 ways: building new bone and, to a lesser degree, slowing down bone loss at the same time.⁹



Are there any serious side effects I should be worried about?

All treatments, including EVENITY®, may have serious side effects. Please see page 11 for a list of the potential side effects with EVENITY®. If you're concerned about any of the side effects, please bring them up with your healthcare provider.



Does my insurance pay for EVENITY®?

What you pay for EVENITY® depends on the type of Medicare insurance you have.^{26,*}

- All Medicare Part B patients are covered[†] for EVENITY®^{27,‡}
- After a deductible is met, Medicare typically picks up 80% of office-administered therapies under Part B²⁸
- You may obtain a supplemental insurance (eg, Medigap) plan to pick up some of the additional 20%^{28,29,§}
- **81%** of Medicare Part B patients have supplemental insurance, meaning they will likely pay **\$0 per dose** of EVENITY®^{26,*}
- You may have additional medical benefit OOP costs related to office visits, facility fees, or administration of EVENITY®. Individual OOP costs will vary

If you have commercial insurance, you may pay as little as \$25 per dose of EVENITY® therapy with the EVENITY® Co-pay Program.^{**} For information about this program, eligibility requirements, and coverage limits, call **800-761-1558** or visit **EVENITYSupport.com**.

Please see Important Safety Information on page 11.

OOP = out-of-pocket.

^{*}Based on Amgen Assist® insurance verification data. Only EVENITY® prospective patients who have opted for Amgen hub services and identified through insurance verification information are included in the analysis. Data is for September 2019 to February 2020.

[†]Covered per the labeled indication.

[‡]Based on DRG coverage data as of February 2020.

[§]Patient should be enrolled in Medicare Part A and Part B. Medicare patients with supplemental coverage (eg, Medigap) may require additional monthly premiums.²⁹

^{**}This program does not provide support for any physician-related services associated with administration of EVENITY®.

Important Safety Information

What is the most important information I should know about EVENITY®?

EVENITY® can cause serious side effects, including increased risk of having a heart attack, stroke, or death from a cardiovascular (heart or blood vessel) problem. Call your healthcare provider or get emergency help right away if you have any of these symptoms: symptoms of **heart attack**, which may include: chest pain or pressure; shortness of breath; feeling light-headed or dizzy; or symptoms of **stroke**, which may include: headache; numbness or weakness in face, arm, or legs; difficulty talking; changes in vision or loss of balance. Before you receive EVENITY®, tell your healthcare provider if you have had a heart attack or stroke, especially if it has happened in the past year.

Do not receive EVENITY® if you: have low blood calcium; or are allergic to romosozumab or any of the ingredients in EVENITY®.

Before receiving EVENITY®, tell your healthcare provider about all your medical conditions, including if you:

- have a history of other heart or blood vessel problems
- have low blood calcium
- cannot take daily calcium and vitamin D
- have kidney problems or are on kidney dialysis
- plan to have dental surgery or teeth removed

What are the possible side effects of EVENITY®?

EVENITY® may cause serious side effects, including:

Serious allergic reactions have happened in people who receive EVENITY®. Call your healthcare provider or go to the nearest emergency room right away if you have any symptoms of a serious allergic reaction including: rash; hives; swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing.

Low calcium levels in your blood (hypocalcemia). EVENITY® may lower the calcium levels in your blood. Your low blood calcium should be treated before you receive EVENITY®. Call your healthcare provider if you have symptoms of low blood calcium such as: spasms, twitches, or cramps in your muscles; numbness or tingling in your fingers, toes or around your mouth.

Severe jaw bone problems (osteonecrosis) may occur. Your healthcare provider should examine your mouth before you start EVENITY® and may tell you to see your dentist. Ask your healthcare provider or dentist about good mouth care.

Unusual thigh bone fractures. Symptoms of this type of fracture include new or unusual pain in your hip, groin, or thigh.

The most common side effects of EVENITY® include joint pain and headaches.

These are not all the possible side effects of EVENITY®. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see EVENITY® full Prescribing Information, including Medication Guide.



You're on your way to helping build new bone

Stay supported throughout your journey and check out **BONE MATTERS®**, your comprehensive support program to provide helpful information. Bone Matters® is with you from the start.



Bone Matters® offers exclusive access to lifestyle tips, educational information, and more to help you achieve your bone health goals while on EVENITY®.

Throughout your EVENITY® treatment, you'll get



Fall prevention tips



Calcium-rich recipes



Exercises to help maintain bone and muscle strength and balance

And more

To learn more, visit [EVENITY.com/signup](https://www.evenity.com/signup) and sign up today.

Please see Important Safety Information on page 11.

References: 1. van Geel TA, van Helden S, Geusens PP, Winkens B, Dinant GJ. Clinical subsequent fractures cluster in time after first fractures. *Ann Rheum Dis*. 2009;68:99–102. 2. US Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services. Office of the Surgeon General; 2004. 3. Inacio MCS, Weiss JM, Miric A, Hunt JJ, Zohman GL, Paxton EW. A community-based hip fracture registry: population, methods, and outcomes. *Perm J*. 2015;19:29–36. 4. National Osteoporosis Society. Life with osteoporosis: the untold story. <https://view.publitas.com/royal-osteoporosis-society/life-with-osteoporosis-the-untold-story>. October 2014. Accessed August 2, 2020. 5. Hansen D, Bazell C, Pelizzari P, Pyenson B. Medicare cost of osteoporotic fractures: the clinical and cost burden of an important consequence of osteoporosis. Milliman Research Report. August 2019. 6. Tajeu GS, Delzell E, Smith W, et al. Death, disability, and destitution following hip fracture. *J Gerontol A Biol Sci Med Sci*. 2014;69:346–353. 7. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25:2359–2381. 8. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. 9. EVENITY® (romosozumab-aqqg) prescribing information, Amgen. 10. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. *Endocr Pract*. 2020;26(suppl 1):1–46. 11. Baniak N, Grzybowski S, Olszynski WP. Dual-energy x-ray absorptiometry scan autoanalysis vs manual analysis. *J Clin Densitom*. 2014;17:97–103. 12. Actonel® (risedronate sodium) prescribing information, Allergan. 13. Atelvia® (risedronate sodium) prescribing information, Allergan. 14. Boniva Injection® (ibandronate sodium) prescribing information, Genentech. 15. Boniva Tablets® (ibandronate sodium) prescribing information, Genentech. 16. Evista® (raloxifene hydrochloride) prescribing information, Eli Lilly. 17. Forteo® (teriparatide) prescribing information, Eli Lilly. 18. Fosamax® (alendronate sodium) prescribing information, Merck. 19. Prolia® (denosumab) prescribing information, Amgen. 20. Reclast® (zoledronic acid) prescribing information, Novartis. 21. Tymlos® (abaloparatide) prescribing information, Radius Health, Inc. 22. National Osteoporosis Foundation. Medication and treatment adherence. www.nof.org/patients/treatment/medicationadherence/. Published September 7, 2018. Accessed August 2, 2020. 23. Data on file, Amgen; [1]; 2020. 24. Fortical® (calcitonin-salmon) prescribing information, Upsher-Smith. 25. National Osteoporosis Foundation. What is osteoporosis and what causes it? <https://www.nof.org/patients/what-is-osteoporosis/>. Accessed August 3, 2020. 26. Data on file, Amgen; [2]; 2020. 27. Data on file, Amgen; [3]; 2020. 28. Medicare.gov. 2020. Medicare costs at a glance. www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance. Accessed August 2, 2020. 29. Medicare.gov. What's Medicare Supplement Insurance (Medigap)? www.medicare.gov/index.php/supplements-other-insurance/whats-medicare-supplement-insurance-medigap. Accessed August 2, 2020.



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Starting your journey

All about you



NAME: _____

DATE: _____

In order to determine the best osteoporosis treatment plan for you, let's review your life needs and goals.

1. TELL ME ABOUT YOUR RESPONSIBILITIES. ARE YOU...?

- ☐ Working ☐ Full-Time ☐ Part-Time
- ☐ Retired
- ☐ Taking care of the household, a spouse/partner, grandchildren, or other family members
- ☐ Other: _____

2. WHAT DOES A GOOD DAY LOOK LIKE FOR YOU? WHAT DO YOU LOVE TO DO?

3. HAVE YOU BEEN TREATED FOR OSTEOPOROSIS IN THE PAST? ☐ Yes ☐ No

If so, what medication? _____

How long were you on it? _____

4. HAVE YOU BROKEN ANY BONES SINCE YOU TURNED 50?

- ☐ Upper arm ☐ Spine ☐ Hip ☐ Wrist ☐ Other ☐ None

5. IF YOU HAVE ANY SPECIFIC CONCERNS ABOUT GETTING ONTO A PRESCRIPTION OSTEOPOROSIS TREATMENT, WHAT ARE THEY?

- ☐ How well it works
- ☐ How it is taken and how often
- ☐ Side effects
- ☐ GI concerns or history
- ☐ Cost
- ☐ Other concerns: _____
- _____

Your personal postmenopausal osteoporosis treatment plan



DATE: _____

Based on our discussion today, including your medical history, your risk factors, and your DXA scan results, my recommendation for treatment of your postmenopausal osteoporosis is as follows:

CALCIUM AND VITAMIN D:

- ☐ Dietary sources: _____
- ☐ Supplemental calcium: _____ mg
- ☐ Supplemental vitamin D: _____ IU

MEDICATION: _____

Dosing: _____

EXERCISE: _____ minutes/daily/weekly

- ☐ Strengthening exercises: weights, resistance bands, etc.
- ☐ Yoga or tai chi
- ☐ Weight-bearing exercises: walking, dancing, etc.
- ☐ Other: _____

FALL PREVENTION TIPS:

- ☐ Wear sensible shoes
- ☐ Remove home hazards (such as small rugs, loose cords, and clutter)
- ☐ Well-lit living space
- ☐ Use assistive devices

FOLLOW-UP DXA SCAN DATE: _____ **RETURN VISIT DATE:** _____

LAB WORK FOLLOW-UP DATE: _____

Notes: _____



Join the Bone Matters® support program for helpful exercise and fall prevention tips, calcium-rich recipes, and more.

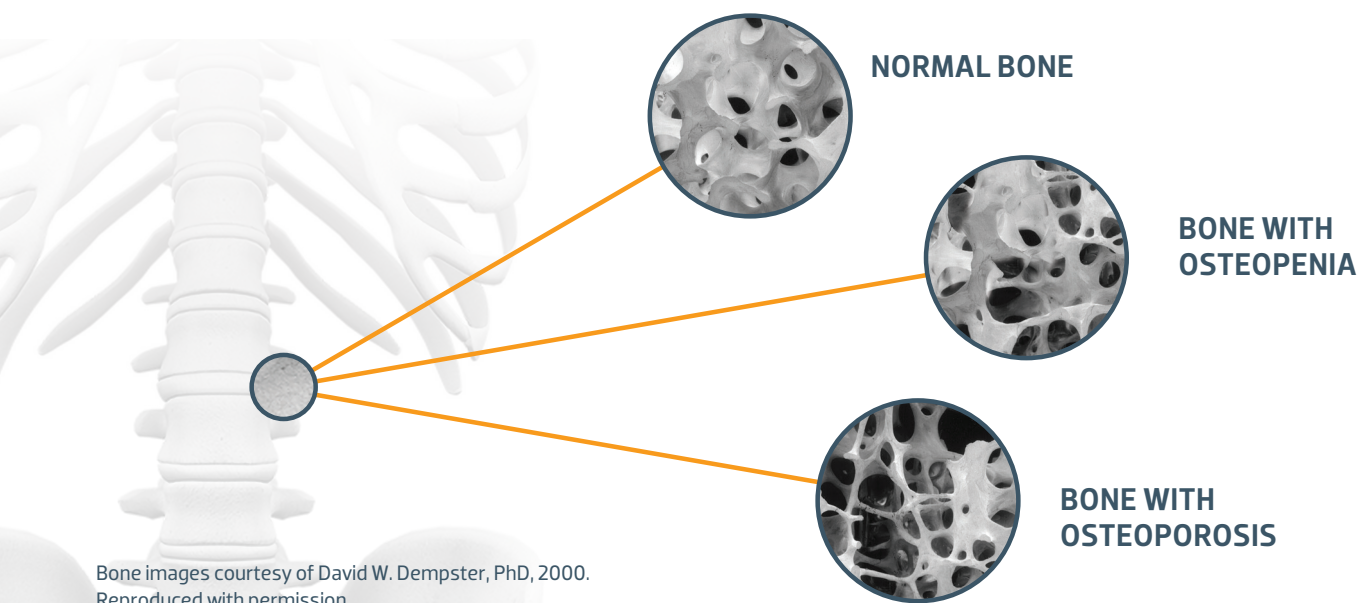
What is osteoporosis?



Osteoporosis ("porous bone") is a bone disease that occurs when your body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall or minor bumps.¹

Osteoporosis is often called a silent disease because you can't feel bones weakening. Breaking a bone is often the first sign of osteoporosis.^{2,3}

Some genetic and lifestyle factors might have contributed to your osteoporosis, such as a parental history of hip fracture, low body weight, or a vitamin D deficiency.^{2,4}



Bone images courtesy of David W. Dempster, PhD, 2000. Reproduced with permission.

There are cells that build bones and cells that remove bone. After menopause, as your estrogen levels decline, the bone removers become more active, creating an imbalance favoring bone loss.^{2,5} There are osteoporosis treatments that can help restore the balance between these two types of cells.^{6,7}

Osteoporosis isn't an inevitable part of aging. You can manage your osteoporosis through prescription treatment and lifestyle changes to help reduce your risk of fracture.^{5,8}

References: 1. National Osteoporosis Foundation. What is osteoporosis and what causes it? <https://www.nof.org/patients/what-is-osteoporosis/>. Accessed August 3, 2020. 2. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. 3. National Institutes of Health. Osteoporosis. <https://www.nia.nih.gov/health/osteoporosis>. Published June 26, 2017. Accessed August 3, 2020. 4. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. *Endocr Pract*. 2020;26(suppl 1):1–46. 5. National Osteoporosis Foundation. What women need to know. <https://www.nof.org/preventing-fractures/general-facts/what-women-need-to-know/>. Accessed August 3, 2020. 6. Pavone V, Testa G, Giardina SMC, Vescio A, Restivo DA, Sessa G. Pharmacological therapy of osteoporosis: a systematic current review of literature. *Front Pharmacol*. 2017;8:803. 7. EVENITY® (romosozumab-aqqg) prescribing information, Amgen. 8. National Institutes of Health. Osteoporosis overview. <https://www.bones.nih.gov/health-info/bone/osteoporosis/overview>. Published October 2018. Accessed August 3, 2020.

