



EVENTITY[®]

(romosozumab) injection

THE TIME IS NOW

In case of a recent fragility fracture,
**BUILD BONE RAPIDLY
WITH EVENTITY FIRST**
to help prevent new fractures.

Then protect with an antiresorptive.*^{1,2}

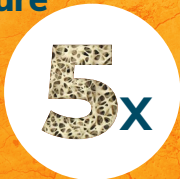


*In the EU and the UK, EVENTITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.^{1,2} Licensed indication may vary between countries. Please consult your local prescribing information before prescribing any drug. **Prescribing information and adverse event reporting are available on pages 6-8 of this material.** Adverse events should be reported. Reporting forms and information can be obtained from your local regulatory authority. Adverse events should also be reported to UCB. **This material is intended for healthcare professionals only.**

There is a critical need to help prevent subsequent fractures in your postmenopausal osteoporosis (PMO) patients⁴

PMO patients are at an increased risk of a subsequent fracture, especially in the first year post fracture.⁵

A postmenopausal woman's risk of a secondary fracture is increased by **5x** in the year following an initial fracture.⁵



Among PMO patients with a hip fracture,

more than 1 in 3 (38.0%) had already suffered a previous fracture.⁴

Analysis of 35,146 women aged 55–90 years who suffered an index fragility fracture in 2013 from Swedish national registries. The cumulative incidence of new fractures within 12 and 24 months following index fracture was assessed.⁴

The possible impact of fragility fractures on quality of life⁶



Pain



Inability to participate in usual activities

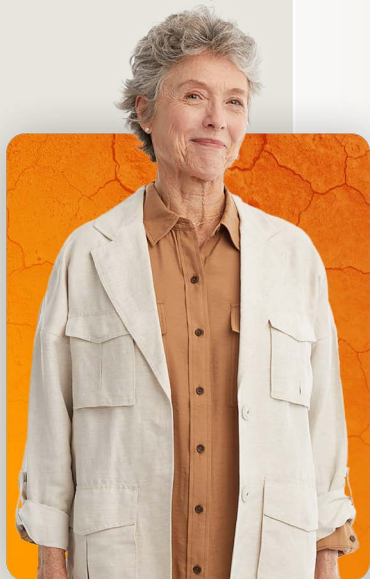


Functional decline



Loss of independence

Postmenopausal women who may benefit from EVENITY have severe osteoporosis and are at high risk of fracture¹



- Recently diagnosed with severe postmenopausal osteoporosis after a vertebral fracture¹
- High risk of another fracture¹
- T-score: -2.9 at lumbar spine, -2.5 at femoral neck²
- No history of myocardial infarction or stroke*¹
- Normal blood calcium*¹

This patient profile is hypothetical and not based on real patients, patient images are used for illustrative purposes only.

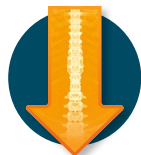
*In the EU and the UK, EVENITY is contraindicated in patients with hypersensitivity to the active substance(s) or any excipients, hypocalcaemia or a history of myocardial infarction or stroke.^{1,3}

EVENITY is the first and only sclerostin inhibitor with the dual effect of building bone and reducing resorption^{1,2,7,8}

Help strengthen your patients' bones with EVENITY first for 12 months then transition to an anti-resorptive, such as alendronate or denosumab, to extend the benefit achieved by EVENITY beyond 12 months^{1,2}

Build bone with EVENITY first for 12 months^{1,2}

Demonstrated significant fracture risk reduction vs alendronate:^{1,2}



4.03% absolute risk reduction
50% relative risk reduction

P<0.001 in new vertebral fractures at Month 24 with romosozumab-to-alendronate vs alendronate alone (co-primary endpoint)*

Romosozumab-to-alendronate showed a significant risk reduction in fractures vs alendronate alone at primary analysis (median 33 months):^{1,2}

- **9.7% vs 13.0%** incidence of clinical fracture (co-primary endpoint; nominal P<0.001)[†]
- **8.7% vs 10.6%** incidence of non-vertebral fracture (nominal P=0.040)[†]
- **2.0% vs 3.2%** incidence of hip fracture (nominal P=0.02)[†]

Rapid and significant improvements in BMD vs alendronate and vs teriparatide^{1,2,9}



Romosozumab improved BMD vs alendronate alone (P<0.001)^{†1,2} and vs teriparatide (primary endpoint; P<0.0001)[§] in just 12 months⁹

*There was a 4.03% ARR (95% CI: 2.50, 5.57), 50% RRR (95% CI: 34, 62) in new vertebral fractures with romosozumab-to-alendronate vs alendronate alone at Month 24. Incidence of new vertebral fracture at Month 24 was 4.1% (n=74/1,825) with romosozumab-to-alendronate vs 8.0% (n=147/1,834) with alendronate alone (adjusted P<0.001).^{1,2,10} [†]At primary analysis (median follow-up approximately 33 months) incidence of clinical fracture was 9.7% (n=198/2,046) with romosozumab-to-alendronate vs 13.0% (n=266/2,047) with alendronate alone (nominal P<0.001), incidence of non-vertebral fracture was 8.7% (n=178/2,046) with romosozumab-to-alendronate vs 10.6% (n=217/2,047) with alendronate alone (nominal P=0.040), and incidence of hip fracture was 2.0% (n=41/2,046) with romosozumab-to-alendronate vs 3.2% (n=66/2,047) with alendronate alone (nominal P=0.02).^{1,2,10} [§]In the ARCH study, patients receiving romosozumab had greater gains in BMD from baseline at all measured sites and all time points than patients receiving alendronate alone. Gains were achieved by Month 12 and maintained at Month 36 after transition from romosozumab to alendronate (P<0.001 for all comparisons).^{1,2} ⁹In the STRUCTURE study, the mean percentage change from baseline in areal BMD by DEXA scan at the total hip through Month 12 was 2.6% in the romosozumab group vs -0.6% in the teriparatide group. (3.2% difference [95% CI: 2.7, 3.8; P<0.0001]).⁹

The safety profile and tolerability of EVENITY was assessed across 19 clinical development programmes¹¹

Summary and frequency of adverse events from the romosozumab Phase 3 clinical trial programme:¹

Frequency	Adverse reaction	MedDRA System Organ Class
Very common	Nasopharyngitis Arthralgia	Infections and infestations Musculoskeletal and connective tissue disorders
Common	Sinusitis Hypersensitivity* Rash Dermatitis Headache Neck pain Muscle spasms Injection site reactions [†]	Infections and infestations Immune system disorders Immune system disorders Immune system disorders Nervous system disorders Musculoskeletal and connective tissue disorders Musculoskeletal and connective tissue disorders General disorders and administration site conditions
Uncommon	Urticaria Hypocalcaemia [‡] Stroke [§] Cataract Myocardial infarction [§]	Immune system disorders Metabolism and nutrition disorders Nervous system disorders Eye disorders Cardiac disorders
Rare	Angioedema Erythema multiforme	Immune system disorders Immune system disorders

Adapted from the EVENITY (romosozumab) Summary of Product Characteristics.¹

Romosozumab is contraindicated in patients with hypersensitivity to the active substance(s) or any excipients, hypocalcaemia or a history of MI or stroke.[‡]

Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000).¹

*Please refer to Contraindication and Special Warnings and Precautions in the Summary of Product Characteristics for more information. [†]The most frequent injection site reactions were pain and erythema. [‡]Defined as albumin adjusted serum calcium that was below the lower limit of normal. [§]Please refer to Myocardial infarction, stroke and mortality in the Summary of Product Characteristics for more information.¹

A treatment journey that keeps life moving¹



1



ONCE MONTHLY

2x subcutaneous 105 mg injections*

Administered one after the other (1 dose)¹

2



FOR 12 MONTHS¹

3



Transition to an anti-resorptive
Such as alendronate or denosumab¹

Treatment should be initiated and supervised by specialist physicians experienced in the management of osteoporosis.¹

Please see the EVENITY Summary of Product Characteristics for further information.

*Administration should be performed by an individual who has been trained in injection techniques.¹

[†]Patients should be adequately supplemented with calcium and vitamin D before and during treatment.¹

EU and UK

Prescribing Information

In the EU and the UK, EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.^{1,3} Licenses may vary by country, please always refer to the Prescribing Information (PI) in your country before prescribing any drug. Adverse events should be reported. Reporting forms and information can be obtained from your local regulatory authority. For UK healthcare professionals, reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to UCB.

The full EU SmPC can be found [HERE](#).

The full UK Prescribing information can be found [HERE](#).

For Irish prescribing information, please scroll to page 7 of this material.

For Czech Republic prescribing information, please scroll to page 8 of this material.



Republic of Ireland

Abbreviated Prescribing Information

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie/homepage/about-us/report-an-issue. Adverse events should also be reported to UCB (Pharma) Ireland Ltd at ucbcares.ie@ucb.com or 1800 930075.

PRESCRIBING INFORMATION FOR HCPs IN REPUBLIC OF IRELAND

(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

EVENTITY® (romosozumab) Active Ingredient: Romosozumab – solution for injection: 105 mg of romosozumab in 1.17 mL of solution (90 mg/mL).

Indications: Severe osteoporosis in postmenopausal women at high risk of fracture.

Dosage and Administration: Treatment should be initiated and supervised by specialist physicians experienced in the management of osteoporosis. Dosage: 210 mg administered as two equal subcutaneous injections of 105 mg each once monthly for 12 months. Patients to be adequately supplemented with calcium and vitamin D before and during treatment. Following completion of therapy, transition to antiresorptive therapy is recommended. Renal impairment: No dose adjustment is needed. Serum calcium to be monitored in patients with severe renal impairment or receiving dialysis. Elderly: No dose adjustment needed. Discontinuation: see SmPC for guidance.

Contraindications, Warnings, Precautions for use: Contraindications: Hypersensitivity to romosozumab or to any of the excipients listed in the SmPC; Hypocalcaemia; History of myocardial infarction or stroke.

Warnings and Precautions: Myocardial infarction and stroke: An increase in serious cases of cardiovascular events has been observed in romosozumab treated patients compared to controls. Consideration should be given to fracture risk over the next year and cardiovascular risk factors. If a patient experiences a myocardial infarction or stroke during therapy, treatment should be discontinued. Hypocalcaemia: Transient hypocalcaemia has been observed. Hypocalcaemia should be corrected prior to initiating romosozumab. Limited safety data in patients with severe renal impairment or receiving dialysis - calcium levels should be monitored in these patients. Hypersensitivity: Erythema multiforme, angioedema and urticaria have been reported. Osteonecrosis of the jaw (ONJ): Consider risk factors when evaluating risk of developing ONJ. Atypical femoral fractures: Atypical low-energy or low trauma fracture of the femoral shaft have been reported rarely. Consider interruption of romosozumab in patients presenting with an atypical femur fracture, based on an individual benefit-risk assessment. **Refer to SmPC for full information.** Interactions: No data available.

Fertility, pregnancy and lactation: Not to be used in child-bearing potential, pregnant or breastfeeding women. Risk for malformations of developing digits in the human foetus in the first trimester, a period when placental transfer of immunoglobulins is limited. No data available on human fertility.

Driving and use of machines: No or negligible influence on ability to drive and use machines.

Adverse Effects: Very Common ($\geq 1/10$): Nasopharyngitis, arthralgia. Common ($\geq 1/100$ to $< 1/10$): Sinusitis, hypersensitivity, rash, dermatitis, headache, neck pain, muscle spasms, injection site reactions. Uncommon ($\geq 1/1,000$ to $< 1/100$): Urticaria, hypocalcaemia, stroke, cataract, myocardial infarction. Rare ($\geq 1/10,000$ to $< 1/1,000$): angioedema, erythema multiforme. See SmPC for further details.

Pharmaceutical Precautions: Store in a refrigerator (2°C – 8°C) in original container, do not freeze. Keep pre-filled pen in the outer carton in order to protect from light. Do not return to refrigerator after use; EVENTITY can be kept at up to 25°C for up to 30 days in original container. Product should be discarded after this period.

Legal Category: POM

Marketing Authorisation Numbers: EU/1/19/1411/001

Marketing Authorisation Holder: UCB Pharma S.A., Allée de la Recherche 60, B-1070 Brussels, Belgium. Further information is available from: Republic of Ireland: UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland Tel: +353 1463 2371 Email: ucbcares.ie@ucb.com

Date of Revision: Aug 2024 (IE-RM-2400111) EVENTITY is a registered trademark.

Czech Republic

Abbreviated Prescribing Information

Zkrácená informace o přípravku EVENTY

Název přípravku: EVENTY 105 mg injekční roztok v předplněné injekční stříkačce.

Kvalitativní a kvantitativní složení: Jedna předplněná injekční stříkačka obsahuje romosozumabum 105 mg v 1,17 ml roztoku (90 mg/ml).

Léková forma: Injekční roztok (injekce).

Terapeutické indikace: Příklad EVENTY je indikován k léčbě těžké osteoporózy u postmenopauzálních žen s vysokým rizikem zlomenin.

Dávkování a způsob podání: Doporučená dávka romosozumabu je 210 mg (podávána ve formě dvou subkutánních injekcí po 105 mg) jednou měsíčně po dobu 12 měsíců. Pacientkám má být před a během léčby adekvátně doplňován vápník a vitamin D. Pacientky vždy obdrží příbalovou informaci a Výstražnou kartu pacienta. Po ukončení léčby romosozumabem se doporučuje přechod na antiresorpční léčbu, aby se prodloužil přínos dosažený romosozumabem i po 12 měsících. K podání dávky 210 mg se použijí 2 subkutánní injekce romosozumabu, které se podávají do oblasti břicha, stehna nebo horní části paže. Druhá injekce se podává okamžitě po první, ale do jiného místa. Aplikaci má provádět osoba, která byla vyškolená v injekčních technikách.

Kontraindikace: Hypersenzitivita na léčivou látku nebo na kteroukoliv pomocnou látku. Hypokalcémie. Infarkt myokardu nebo cévní mozková příhoda v anamnéze.

Zvláštní upozornění a opatření pro použití: **Infarkt myokardu a cévní mozková příhoda:** V randomizovaných kontrolovaných studiích byl pozorován vyšší výskyt závažných kardiovaskulárních příhod (infarkt myokardu a cévní mozková příhoda) u pacientek léčených romosozumabem ve srovnání s kontrolními skupinami. Při rozhodování, zda použít romosozumab u konkrétní pacientky, se má zvážit riziko zlomenin pro nadcházející rok a riziko kardiovaskulárních příhod u této pacientky na základě rizikových faktorů (např. zjištěné kardiovaskulární onemocnění, hypertenze, hyperlipidemie, diabetes mellitus, kouření, těžká porucha funkce ledvin, věk). Romosozumab se má použít pouze v případech, že předepisující lékař a pacientka souhlasí, že přínos převažuje nad rizikem. Pokud dojde u pacientky během léčby k infarktu myokardu nebo cévní mozkové příhodě, je nutné léčbu romosozumabem ukončit. **Hypokalcémie:** U pacientek léčených romosozumabem byla pozorována přechodná hypokalcémie. Hypokalcémie musí být korigována před zahájením léčby romosozumabem a pacientky je třeba sledovat pro případný výskyt známek a příznaků hypokalcémie. Pokud se u pacientek objeví suspektní příznaky hypokalcémie během léčby, je třeba měřit hladiny vápníku. Pacientkám má být adekvátně doplňován vápník a vitamin D. **Hypersenzitivita:** V klinických studiích ve skupině s romosozumabem se vyskytly klinicky významné hypersenzitivní reakce, včetně angioedému, multiformního erytému a urtikárie. Pokud dojde k anafylaktické nebo jiné klinicky významné alergické reakci, musí být zahájena vhodná léčba a ukončeno podávání romosozumabu. **Osteonekróza čelisti (ONJ, osteonecrosis of the jaw):** ONJ byla vzácně hlášena u pacientek léčených romosozumabem. Všem pacientkám má být doporučeno, aby udržovaly dobrou hygienu ústní dutiny, chodily pravidelně na zubní prohlídky a okamžitě hlásily jakékoliv ústní příznaky, jako je pohyblivost zubů, bolest, otok nebo nehojící se vředy či výtok během léčby romosozumabem. **Atypické zlomeniny femuru:** U pacientek léčených romosozumabem byla vzácně hlášena atypická zlomenina diafýzy femuru spojená s malým traumatem (tzv. low-energy trauma fracture), která se může vyskytnout i spontánně. U každé pacientky, která se dostaví s novými nebo neobvyklými bolestmi stehna, kyčle nebo třísla, má být podezření na atypickou zlomeninu a pacientka má být vyšetřena, aby se vyloučila neúplná zlomenina femuru.

Interakce s jinými léčivými přípravky: S romosozumabem nebyly provedeny žádné studie interakcí. U romosozumabu nejsou očekávány žádné farmakokinetické interakce.

Těhotenství, kojení a fertilita: Romosozumab není indikován k použití u žen ve fertilním věku a těhotných žen. Údaje o podávání těhotným ženám nejsou k dispozici. Romosozumab není indikován k použití u kojících žen. Informace o vyloučení romosozumabu do lidského mateřského mléka nejsou k dispozici. Nejsou k dispozici žádná data o účincích romosozumabu na fertilitu u člověka.

Nežádoucí účinky: Nejčastější nežádoucí účinky byly nazofaryngitida (13,6 %) a artralgie (12,4 %). Reakce související s hypersenzitivitou se vyskytly u 6,7 % pacientek léčených romosozumabem. Hypokalcémie byla hlášena méně často (u 0,4 % pacientek léčených romosozumabem). V randomizovaných kontrolovaných studiích bylo pozorováno zvýšení závažných kardiovaskulárních příhod (infarkt myokardu a cévní mozková příhoda) u pacientek léčených romosozumabem v porovnání s kontrolními skupinami.

Inkompatibility: Studie kompatibility nejsou k dispozici, a proto nesmí být tento léčivý přípravek mísen s jinými léčivými přípravky.

Zvláštní opatření pro uchovávání: Uchovávejte v chladničce (2 °C – 8 °C), chráňte před mrazem a světlem, s přípravkem netřepajte. Před podáním nechte roztok ohřát na pokojovou teplotu. Po vjmutí z chladničky se přípravek EVENTY nesmí do chladničky vrátit, ale může být uchováván v původním obalu při pokojové teplotě (do 25 °C) po dobu až 30 dnů. Není-li použit do této doby, přípravek musí být zlikvidován.

Držitel rozhodnutí o registraci: UCB Pharma S.A., Allée de la Recherche 60, B-1070 Bruxelles, Belgie.

Registrační číslo: EU/1/19/1411/003

Datum revize textu: 22. srpna 2024.

Před předepsáním přípravku, se prosím seznamte s úplným zněním Souhrnu údajů o přípravku. Výdej léčivého přípravku je vázán na lékařský předpis. Přípravek je hrazen z prostředků veřejného zdravotního pojištění.

SC-CZ-AMG785-00022

URČENO PRO ODBORNOU VEŘEJNOST.

Amgen s.r.o., Pod dráhou 1637/2, Holešovice, 170 00 Praha 7, Tel.: +420 221 773 500, www.amgen.cz

Footnotes:

ARCH study design: The ARCH study is a Phase 3 multicentre, multinational, randomised, double-blind study assessing the safety and efficacy of EVENITY (n=2,046) vs alendronate (n=2,047) in 4,093 postmenopausal women who were diagnosed with severe osteoporosis and had suffered previous fractures. Patients were assigned randomly in a 1:1 ratio to receive monthly subcutaneous EVENITY injection (210 mg) or weekly oral alendronate (70 mg) in a blinded fashion for 12 months, followed by open-label alendronate in both groups. Primary endpoints included the cumulative incidence of new vertebral fractures through Month 24 and the cumulative incidence of clinical fractures (non-vertebral and symptomatic vertebral fracture) at primary analysis (after clinical fractures had been confirmed in ≥ 330 patients).²

STRUCTURE study design: The STRUCTURE study was a randomised, Phase 3b, open-label, active-controlled, parallel group study in 436 women aged ≥ 55 to ≤ 90 years with postmenopausal osteoporosis who have received a previous oral bisphosphonate at least 3 years before screening and alendronate the year before screening. Patients were randomised (1:1) to receive once monthly 210 mg subcutaneous EVENITY (n=218) or once daily 20 μ g subcutaneous teriparatide (n=218). The primary endpoint of percentage change from baseline in areal BMD by DEXA scan at the total hip through Month 12.^{1,9}

Acronyms:

ARR, absolute risk reduction; **BMD**, bone mineral density; **CI**, confidence interval; **DEXA**, dual-energy X-ray absorptiometry; **EU**, European Union; **HCP**, healthcare professional; **MedDRA**, Medical Dictionary for Regulatory Activities; **MI**, myocardial infarction; **RRR**, relative risk reduction; **UK**, United Kingdom.

References:

1. EVENITY (romosozumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/evenity-epar-product-information_en.pdf. Accessed March 2026.
2. Saag KG, et al. *N Engl J Med*. 2017;377(15):1417–27.
3. EVENITY (romosozumab) UK SmPC. <https://www.emcpi.com/pi/37322>. Accessed March 2026.
4. Toth E, et al. *J Bone Miner Res*. 2020;35(5):861–68.
5. van Geel TACM, et al. *Ann Rheum Dis*. 2009;68(1):99–102.
6. Gold T, et al. *J Drug Assess*. 2019;8(1):175–183.
7. Cosman F, et al. *N Engl J Med*. 2016;375(16):1532–43.
8. Rosen CJ. *N Engl J Med*. 2017;377(15):1479–80.
9. Langdahl BL, et al. *Lancet*. 2017;390(10102):1585–94.
10. Saag KG, et al. *N Engl J Med*. 2017;377(15):1417–27. (Supp).
11. EVENITY European Public Assessment Report. Available at: https://www.ema.europa.eu/en/documents/assessment-report/evenity-epar-public-assessment-report_en.pdf. Accessed: March 2026.

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GL-DC-2600050 | Date of preparation: March 2026