EVENITY®▼
(romosozumab) injection

After fragility fracture

Who could benefit from a treatment sequence starting with EVENITY® first?

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

You can also report side effects directly via http://mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd via UCBCares© on +44 (0) 1753 7777 100 or 0800 279 3177 (freephone)

EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[1]

The **most common adverse reactions** are nasopharyngitis and arthralgia. EVENITY is **contraindicated** in patients with hypersensitivity, hypocalcaemia and history of myocardial infarction or stroke.[1]

REFERENCES | PI-GB | PI-NI/ROI

› MEET THE PATIENTS

EVENITY®
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The way you start your patients' treatment sequence can help optimise outcomes

Anne

Suffered a clinical vertebral fracture

› Help her keep going

Maria

Suffered a major osteoporotic hip fracture

› Help her stay independent

Geeta

Suffered a major osteoporotic humerus fracture

› Help her not miss out

The clinical information in these patient profiles are based on example clinical cases provided in the Consensus advisory statement from the NOGG and ROS[2]

› See recommendations

EVENITY is contraindicated in patients with hypersensitivity, hypocalcaemia and history of myocardial infraction or stroke.[1]

Patient images are not based on real individuals and are for illustrative purposes only.

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Postmenopausal women who are suffering with painful fractures...

...could benefit from EVENITY

"I don't want to end up like my mum, who was disabled by severe back pain in her later years and became very stooped."*

- Had a recent clinical vertebral fracture
- Never treated for osteoporosis
- T-score -3.5 at lumbar spine and -2.7 at femoral neck
- FRAX-indicated 10-year probabilities (adjusted for recent fracture): 39% for MOF and 16% for hip fracture

Why treat with EVENITY?

- The risk of a subsequent fracture is highest in the first year after a previous fracture[3]
- EVENITY provided superior fracture risk reduction vs alendronate in the ARCH study,[†] where 91% of patients were bone-specific treatment-naïve[‡4,5]
- Significantly more patients achieved a >-2.5 or >-2.0 T-score at Month 12 at total hip, femoral neck, or lumbar spine with EVENITY compared to alendronate[‖6]

› Watch the ARCH animation

The clinical information in this patient profile are based on example clinical cases provided in the Consensus advisory statement from the NOGG and ROS.[2]

Patient image is not based on a real individual and is for illustrative purposes only.

*Patient quote adapted from an example clinical case provided in the Consensus advisory statement from the NOGG and ROS.[2] †In vertebral, clinical and non-vertebral fractures, including hip.[4] ‡History of medication collected as part of medical history recorded at screening visit. ARCH was a Phase 3, multi-centre, international, randomised, double-blind trial in 4093 postmenopausal women aged 55 to 90 years with severe osteoporosis. The co-primary endpoints were incidence of new vertebral fracture through Month 24 and incidence of clinical fracture at primary analysis (median time 33 months).[4] ‖ In a secondary, post-hoc analysis of ARCH: Patients achieving T-score >-2.5 at 12 months: Lumbar spine – EVENITY 62.8% (n=1021/1625), alendronate 42.0% (n=675/1608), P<0.001; Total hip – EVENITY 54.6% (n=918/1680), alendronate 43.8% (n=728/1663), P<0.001; Femoral neck – EVENITY 40.2% (n=676/1680), alendronate 26.0% (n=432/1663), P<0.001. Patients achieving T-score >-2.0 at 12 months: Lumbar spine – EVENITY 45.3% (n=737/1626), alendronate 26.7% (n=429/1608), P<0.001; Total hip – EVENITY 23.9% (n=401/1680), alendronate 14.7% (n=245/1663), P<0.001; Femoral neck – EVENITY 7.7% (n=676/1680), alendronate 5.1% (n=85/1663), P<0.001.[6]

EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[1]

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Postmenopausal women who are suffering with the burden of a hip fracture...

...could benefit from EVENITY

"I have to be very careful now. I know that my back is weak and I'm very afraid of it happening again."

- Had a recent wrist and hip fracture
- Had longstanding back pain and multiple vertebral fractures were confirmed
- T-score -2.9 at lumbar spine
- FRAX-indicated 10-year probabilities (adjusted for recent fracture): 47% for MOF and 20% for hip fracture

Why treat with EVENITY?

- Hip fractures have a high burden of disease, with an average 20-day hospital stay and an estimated cost of >£10,000 for each hip fracture in the NHS[7,8]
- EVENITY for 12 months followed by alendronate demonstrated superior fracture risk reduction vs alendronate alone in vertebral,*clinical and non-vertebral fractures, including hip[1,4]
- Starting with EVENITY can help rapidly increase BMD at lumbar spine and total hip, with significant benefits vs alendronate† and teriparatide‡ observed at 12 months and as early as 6 months[1,4,9]

› Watch the ARCH animation

The clinical information in this patient profile are based on example clinical cases provided in the Consensus advisory statement from the NOGG and ROS.[2]

Patient image and quote are not based on a real individual and are for illustrative purposes only.

*vs 24 months of alendronate alone. ARCH was a Phase 3, multi-centre, international, randomised, double-blind trial in 4093 postmenopausal women aged 55 to 90 years with severe osteoporosis. The co-primary endpoints were incidence of new vertebral fracture through Month 24 and incidence of clinical fracture at primary analysis (median time 33 months).[4] †Difference in BMD vs alendronate at 12 months: Lumbar spine: 7.4% (EVENITY: 12.4%; alendronate: 5.0%); Total hip: 2.9% (EVENITY: 5.8%; alendronate: 2.9%). ‡Difference in BMD vs teriparatide at 12 months: Lumbar spine: 4.4% (EVENITY: 9.8%; teriparatide: 5.4%); Total hip: 3.4% (EVENITY: 2.9%; alendronate: -0.5%).

EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[1]

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Postmenopausal women who are suffering with painful fractures and low T-scores...

...could benefit from EVENITY

"Now I am very cautious. The worst part was not being able to participate in activities I enjoy."

- Had a recent humerus fracture after slipping
- T-score -3.5 at lumbar spine and -3.4 at total hip
- FRAX-indicated 10-year probabilities: 47% for MOF and 23% for hip fracture

Why treat with EVENITY?

- Non-displaced proximal humeral fractures are among the most common fractures associated with osteoporosis in postmenopausal women, and they can be a major cause of functional disability and reduction in subjective patient-perceived health[10]
- EVENITY for 12 months followed by alendronate demonstrated superior fracture risk reduction vs alendronate alone in vertebral,* clinical and non-vertebral fractures[1,3]
- Starting with EVENITY can significantly help more patients achieve a non-osteoporotic T-score at total hip, femoral neck, or lumbar spine vs alendronate at 12 months[6†]

› Watch the ARCH animation

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Patient image and quote are not based on a real individual and are for illustrative purposes only.

*vs 24 months of alendronate alone. ARCH was a Phase 3, multi-centre, international, randomised, double-blind trial in 4093 postmenopausal women aged 55 to 90 years with severe osteoporosis. The co-primary endpoints were incidence of new vertebral fracture through Month 24 and incidence of clinical fracture at primary analysis (median time 33 months).[4] †Secondary, post-hoc analysis of ARCH: Patients achieving T-score >-2.5 at 12 months: Lumbar spine – EVENITY 62.8% (n=1021/1625), alendronate 42.0% (n=675/1608), P<0.001; Total hip – EVENITY 54.6% (n=918/1680), alendronate 43.8% (n=728/1663), P<0.001; Femoral neck – EVENITY 40.2% (n=676/1680), alendronate 26.0% (n=432/1663), P<0.001. Patients achieving T-score >-2.0 at 12 months: Lumbar spine – EVENITY 45.3% (n=737/1626), alendronate 26.7% (n=429/1608), P<0.001; Total hip – EVENITY 23.9% (n=401/1680), alendronate 14.7% (n=245/1663), P<0.001; Femoral neck – EVENITY 7.7% (n=676/1680), alendronate 5.1% (n=85/1663), P<0.001.[6]

EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[1]

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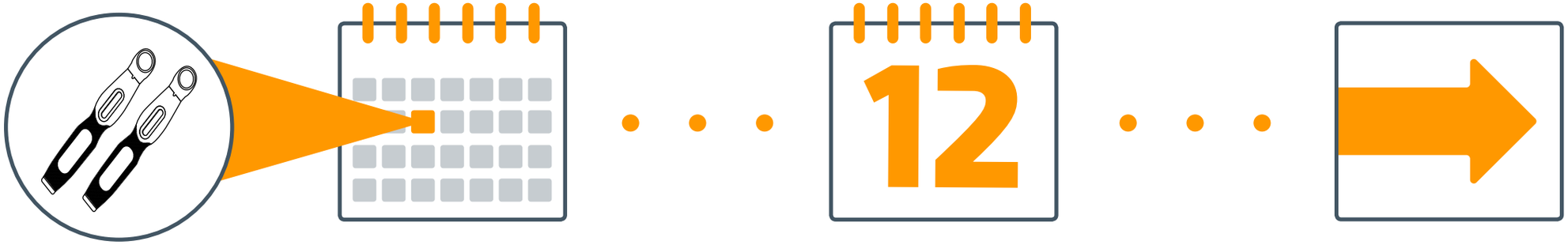
How do you treat your patients with EVENITY first?



2 INJECTIONS* **(1 DOSE)**

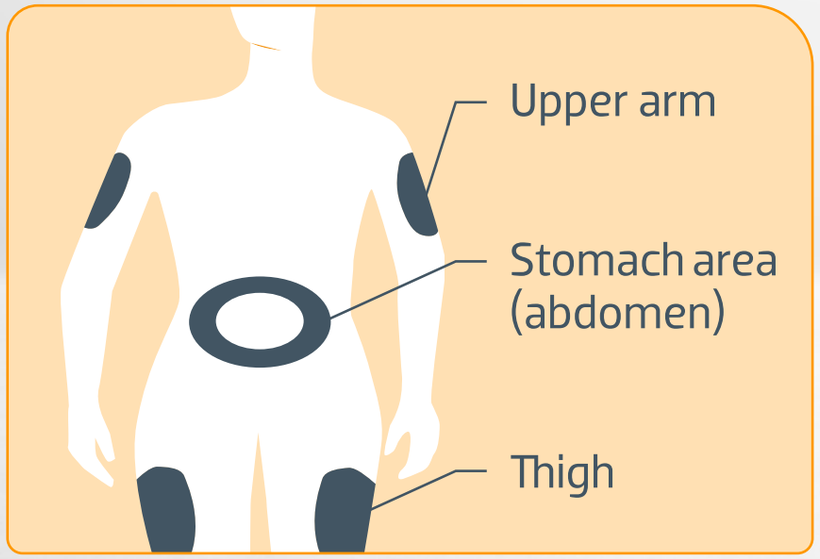
ONCE A MONTH†

FOR 12 MONTHS

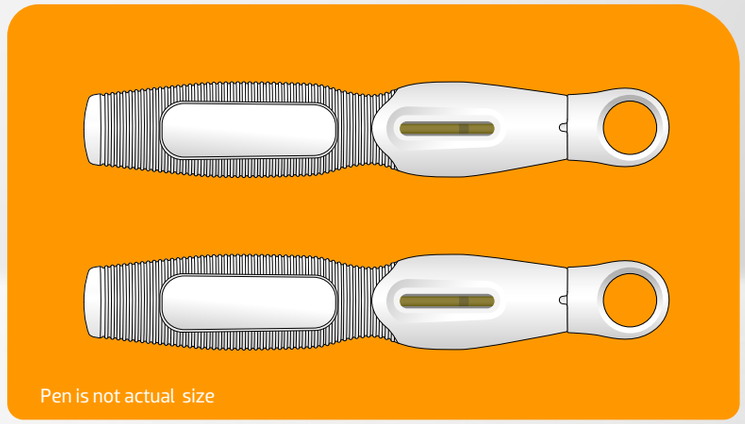
TRANSITION TO AN ANTI-RESORPTIVE

Patients should be adequately supplemented with calcium and vitamin D before and during treatment.[1]
Treatment should be initiated and supervised by specialist physicians experienced in the management of osteoporosis.[1]

Where do I administer EVENITY?



EVENITY should be injected in either the stomach area (abdomen) or thigh. The outer area of the upper arm can also be used as an injection site.‡



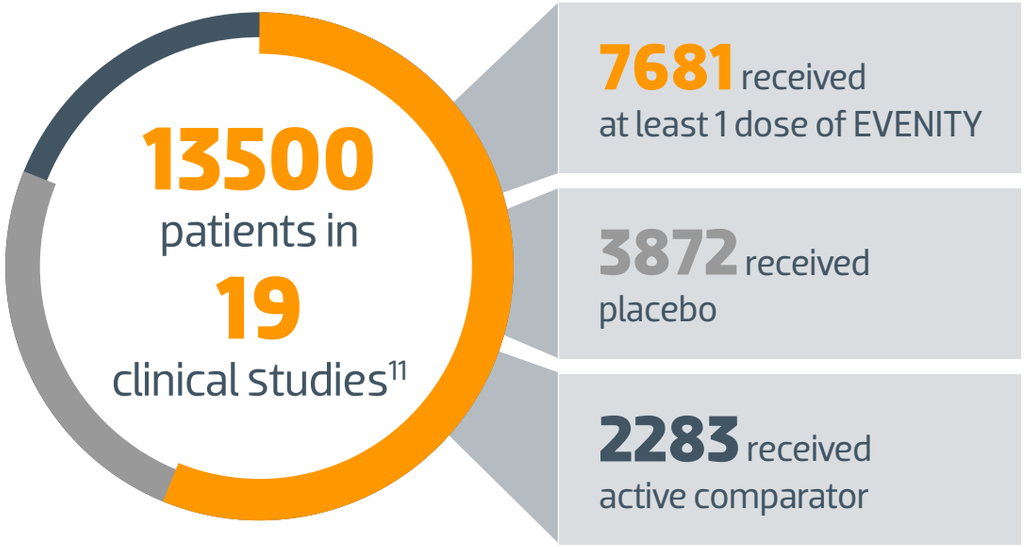
› How to administer EVENITY

*Administration should be performed by an individual who has been trained in injection techniques. †Each monthly dose of EVENITY is comprised of two subcutaneous injections of 105 mg each (administered one right after the other). ‡The second injection must be given immediately after the first one but at a different injection site. If the same injection area is planned to be used for the second injection, a different injection spot should be used. EVENITY should not be injected into areas where the skin is tender, bruised, red, or hard.

EVENITY®
(romosozumab) injection

The safety and tolerability data of EVENITY are based on an extensive clinical trial programme[1,11]

The EVENITY safety database included over:[11]



Frequency	Adverse reaction	MedDRA System Organ Class[1]
Very common (≥1/10)	Nasopharyngitis Arthralgia	Infections and infestations Musculoskeletal and connective tissue disorders
Common (≥1/100 to <1/10)	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 Administration site conditions
Uncommon (≥1/1,000 to <1/100)	Urticaria Hypocalcaemia‡ Stroke§ Cataract Myocardial infarction§	Immune system disorders Metabolism and nutrition disorders Nervous system disorders Eye disorders Cardiac disorders
Rare (≥1/10,000 to <1/1,000)	Angioedema Erythema multiforme Atypical femoral fracture Osteonecrosis of the jaw	Immune system disorders Immune system disorders

*Please refer to Contraindications 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 death in the Summary of Product Characteristics for more information.

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EVENITY contraindications, warnings and precautions

Contraindications[1]

- Hypersensitivity to the active substance(s) or to any of the excipients
- Hypocalcaemia
- History of myocardial infarction or stroke

Special warnings and precautions for use[1]

Myocardial infarction and stroke

In randomised controlled studies, an increase in serious cardiovascular events (myocardial infarction and stroke) has been observed in EVENITY treated patients compared to controls

EVENITY is contraindicated in patients with previous myocardial infarction or stroke

When determining whether to use EVENITY for an individual patient, consideration should be given to her fracture risk over the next year and her cardiovascular risk based on risk factors (e.g. established cardiovascular disease, hypertension, hyperlipidaemia, diabetes mellitus, smoking, severe renal impairment, age)

EVENITY should only be used if the prescriber and patient agree that the benefit outweighs the risk.
If a patient experiences a myocardial infarction or stroke during therapy, treatment with romosozumab should be discontinued

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Refer to the SmPC for other warnings and precautions

EVENITY®
(romosozumab) injection

Start your patients' treatment sequence with EVENITY[1,4]

Who is EVENITY for?

EVENITY is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture[1]

What is the treatment journey?

EVENITY dosing is 2 injections (1 dose, 210 mg), once monthly for 12 months before transitioning to an anti-resorptive[1]

How could they benefit?

EVENITY first for 12 months followed by alendronate provides superior fracture risk reduction vs alendronate alone in vertebral, clinical and non-vertebral fractures, including hip[1,4]

Think EVENITY first after fragility fracture

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References

1. EVENITY SmPC.
2. NOGG. Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. 30 May 2022. Available at: https://strwebprdmedia.blob.core.windows.net/media/0h3jlog5/nogg-ros-romosozumab-statement-may-2022.pdf. Accessed December 2022.
3. Van Geel T, et al. *Ann Rheum Dis*. 2009;68:99-102.
4. Saag KG, et al. *N Engl J Med*. 2017;377:1417-1427.
5. Data on file. CSR20110142. Page 276 –Table 14-2.7.
6. Cosman F, et al. *J Bone Miner Res*. 2020;35:1333-1342.
7. Royal College of Physicians. National Hip Fracture Database annual report 2018. Available at: https://www.nhfd.co.uk/files/2018ReportFiles/NHFD-2018-Annual-Report-v101.pdf. Accessed December 2022.
8. Leal J, et al. *Osteoporos Int*. 2016;27:549-558.
9. Langdahl BL, et al. *Lancet*. 2017;390:1585-1594.
10. Calvo E, et al. *J Shoulder Elbow Surg*. 2011;20:795-801.
11. EVENITY EPAR.

Prescribing information – GB

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PRESCRIBING INFORMATION FOR HCPs IN GREAT BRITAIN
(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

EVENITY® ▼ (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. *Hypocalcemia:* 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 (≥ 1/10):* Nasopharyngitis, arthralgia. *Common (≥ 1/100 to < 1/10):* Sinusitis, hypersensitivity, rash, dermatitis, headache, neck pain, muscle spasms, injection site reactions. *Uncommon (≥ 1/1,000 to < 1/100):* Urticaria, hypocalcaemia, stroke, cataract, myocardial infarction. *Rare (≥ 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; EVENITY 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:** PLGB 00039/0793 **UK NHS Costs:** 2 pre-filled pens (£427.75) **Marketing Authorisation Holder:** UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, United Kingdom. **Further information is available from:** UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. *Tel:* +44 (0)1753 777100 *Email:* ucbcares.uk@ucb.com

Date of Revision: November 2022 (GB-P-RM-OP-2200254) EVENITY is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd.

For more information, visit UCBCares® at **ucbcares.co.uk**

UCBCares®

Please refer to the full Prescribing Information before prescribing EVENITY.

To access the PI, scan the QR code on the left or visit:
https://www.evenity.co.uk/prescribing-information

EVENITY® ▼
(romosozumab) injection

Prescribing information – NI and ROI

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PRESCRIBING INFORMATION FOR HCPs IN REPUBLIC OF IRELAND AND NORTHERN IRELAND

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

EVENITY® ▼ (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. *Hypocalcemia*: 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 (≥ 1/10)*: Nasopharyngitis, arthralgia. *Common (≥ 1/100 to < 1/10)*: Sinusitis, hypersensitivity, rash, dermatitis, headache, neck pain, muscle spasms, injection site reactions. *Uncommon (≥ 1/1,000 to < 1/100)*: Urticaria, hypocalcaemia, stroke, cataract, myocardial infarction. *Rare (≥ 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; EVENITY 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 **UK NHS Costs:** 2 pre-filled pens (£427.75) **Marketing Authorisation Holder:** UCB Pharma S.A., Allée de la Recherche 60, B-1070 Brussels, Belgium. **Further information is available from:** *Northern Ireland:* UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. *Tel:* +44 (0)1753 777100 *Email*: ucbcares.uk@ucb.com *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: November 2022 (IE-P-RM-OP-2200011) EVENITY is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard for Northern Ireland and www.hpra.ie/homepage/about-us/report- an-issue for Ireland. Adverse events should also be reported to UCB Pharma Ltd.

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