PATIENT INFORMATION ON
ROMOSOZUMAB
[Romo-SOZ-you-mab]

(Brand name: Evenity®)

This information sheet was written by the Australian Rheumatology Association to help you understand romosozumab. It includes important information about:
- **how you should use your medication**
- **the possible side (harmful) effects**
- **other precautions you should take while you are taking romosozumab.**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER
- You must see your rheumatologist/GP regularly to make sure the treatment is working and check for possible side effects.
- If you are worried about any side effects, you should contact your rheumatologist/GP as soon as possible.
- Do not stop using romosozumab until advised by your rheumatologist/GP.

For more information about OSTEOPOROSIS see the Healthy Bones Australia website www.osteoporosis.org.au/ or phone Osteoporosis Australia on 1800 242 141

What is romosozumab?
Romosozumab (brand name Evenity®) is a medication used to treat osteoporosis (bone loss). Osteoporosis is a common condition which causes bones to become fragile and brittle so that they break (fracture) more easily. Fractures are painful and restrict a person's ability to carry out their normal daily tasks. Romosozumab reduces the risk of a broken bone or fracture.

What benefit can you expect from your treatment?
You will likely not feel any different after taking romosozumab. Taking romosozumab help to increase bone strength and reduce the chance of fracture.

Stopping romosozumab
If you stop or delay your romosozumab treatment, your disease may get worse. Keep taking your treatment, unless advised by your rheumatologist to stop or unless serious side effects occur (see Side effects).

If you stop romosozumab for any reason you **must** contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.

How will you be checked while on romosozumab?
Medications like romosozumab are very expensive and are highly funded by Medicare. Certain conditions must be met to receive it.

Romosozumab will only be given if your osteoporosis is severe (very low bone mineral density) and you are at high risk of a fracture (i.e. have already had a fracture).

A blood test is needed before starting your treatment. Regular blood tests are not required, however may be requested by your doctor if you suffer any side effects.

How is romosozumab taken?
Romosozumab is injected just under the skin of the thigh or abdomen (subcutaneously). It is best to avoid (if possible) any areas of skin with rashes, skin breaks, tenderness, hardness or bruising.

The prefilled autoinjector or syringe should be taken out of the refrigerator 30 minutes before injecting to allow it to reach room temperature. Do not heat it in other ways (e.g. microwave). Do not shake or freeze the injection.

Romosozumab can be injected by your doctor, nurse, carer, or by yourself. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is important to change the injection site each time.

When should it be taken?
Romosozumab should be taken as two subcutaneous injections every month.

If you miss an injection: have the next injection as soon as you remember, then subsequent

injection a month later and then continue as you normally would with monthly injections. Do not inject a double dose to make up for a missed dose. If you have missed more than one dose or are not sure what to do, check with your doctor or pharmacist.

What is the dosage?

Romosozumab is a solution for injection that comes in a pre-filled syringe or autoinjector 'pen' device. Each injection contains 105mg of romosozumab. For osteoporosis fracture risk reduction, the usual dose of romosozumab is 210mg (two pens at a time) injected each month for 12 months. The benefit of romosozumab past 12 months is not known.

It is common to change to an anti-resorptive treatment such as denosumab (Prolia®) or zoledronic acid (Aclasta®) after the 12 month course of romosozumab to 'lock in' the improvement in bone strength.

Can other medications be taken with romosozumab?

Romosozumab may be used alone or with other arthritis medications including:
- other disease modifying anti rheumatic drugs (DMARDs) such as methotrexate
- steroid medications such as prednisolone or cortisone injections into the joint
- anti-inflammatory medications (NSAIDs) such as naproxen (Naprosyn®) or ibuprofen (Brufen®, Nurofen®)
- simple pain medications such as paracetamol.

Romosozumab should not be used at the same time as other bone strengthening medications such as alendronate (Fosamax®, risedronate (Apotex®), zoledronic acid (Aclasta® or denosumab (Prolia®).

Are there any side effects?

Romosozumab is generally very well tolerated, but everyone is different and you might experience side effects with your treatment. Tell your doctor if you notice side effects that you think are caused by this medication. Many side effects disappear when romosozumab treatment is stopped.

Most common side effects
- In clinical trials, patients taking romosozumab reported upper respiratory tract (nose, throat and sinus) infections.

  These infections occurred at almost the same rate as people not taking romosozumab. Some infections may need

treatment and romosozumab may need to be stopped for a while if you develop an infection, so it is important to contact your doctor for advice.
- Arthralgia (joint/back pain) was also commonly reported in patients taking romosozumab, however at a similar rate to people not taking the medication.
- Injection site reaction (redness, bruising) is common.

What precautions are necessary?

Hypocalcaemia (low calcium)
- Your blood may become low in calcium if you start taking romosozumab without adequate vitamin D and calcium. People low in calcium often report lip or hands/feet tingling, as well as muscle cramps.
- Your doctor will normally recommend taking a vitamin D and calcium supplement prior to and during romosozumab treatment.

Myocardial infarction (heart attack) and stroke
- One early clinical trial for romosozumab showed an increase in heart attacks and strokes in people taking romozosumab compared to those who were not. Other studies have not shown a similar increase in these events.
- If you have a history of heart disease or stroke, you should talk to your doctor about this before starting romosozumab.
- Romosozumab is not recommended if you have had a heart attack or stroke within the last 12 months.

Osteonecrosis of the jaw
- Damage to the jaw bone occurs occasionally in people using romosozumab, usually when they have a tooth extraction and/or local infection.
- Patients should discuss the risks/benefits of the dental procedure with their dentist.

Atypical femur fracture
- Very rarely, long-term use of bone-strengthening medications can cause a fracture in the middle of the femur (long bone of the leg). Please let your doctor know if you have any persistent discomfort in your thigh when taking romosozumab.

Vaccines
- If you are taking romosozumab you should have any vaccines that you have been recommended.

- COVID-19 and pneumococcal vaccines and the yearly seasonal flu vaccinations are encouraged.

- For more information on vaccination including the COVID-19 vaccination go to the ARA website: https://rheumatology.org.au/For-Patients/Adult-Medication-Information/Vaccinations-in-Rheumatology

Surgery
- No break in treatment is required if you are due to undergo surgery.

Use in pregnancy and when breastfeeding
- It is important to discuss with your doctor if you are planning a pregnancy while on romosozumab.
- There have been no clinical studies using romosozumab in pregnant women, so the risk to the baby is unknown.
- Do not breastfeed if you are taking romosozumab as it is uncertain how much of the medication might be excreted in breastmilk.
- More detailed information is available at: https://rheumatology.org.au/gps/documents/ARAPrescribersinfoonmedicationsinpregnancy27Apr21_Final.pdf

How to store romosozumab
- Store romosozumab in the refridgerator at between 2 and 8 degrees.
- It is recommended to allow romosozumab to come to room temperature before it is administered.
- Keep all medications out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

Arthritis AUSTRALIA