Ponlimsi™
(denosumab-adet)
Injection • 60mg/mL

PONLIMSI REMS | PATIENT GUIDE

What is PONLIMSI?

PONLIMSI (denosumab-adet) injection, for subcutaneous use, is a prescription medicine used to:

- Treat osteoporosis (thinning and weakening of bone) in women after menopause ("change of life") who:
  - Are at high risk for fracture (broken bone)
  - Cannot use another osteoporosis medicine or other osteoporosis medicines did not work well
- Increase bone mass in men with osteoporosis who are at high risk for fracture
- Treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body
- Treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body
- Treat osteoporosis in men and women who will be taking corticosteroid medicines (such as prednisone) for at least 6 months and are at high risk of fracture

What is the serious risk of PONLIMSI?

Patients with advanced chronic kidney disease, including dialysis-dependent patients, are at risk of severe hypocalcemia (low calcium levels in your blood) following PONLIMSI administration.

Most people with low blood calcium levels do not have symptoms, but some people may have symptoms which include:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Call your doctor right away if you think you may be having any of these symptoms.

What to expect before and during PONLIMSI treatment:

- Talk to your doctor before starting PONLIMSI.
- If you have low blood calcium before you start receiving PONLIMSI, it may get worse during treatment.
- Your low blood calcium must be treated before you receive PONLIMSI.
- Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take PONLIMSI. Take calcium and vitamin D as your doctor tells you to.
- If you have advanced chronic kidney disease (may or may not be on kidney dialysis), PONLIMSI may increase your risk for severe low calcium levels in your blood, leading to hospitalization, life-threatening events, and death.
- A mineral and bone disorder associated with kidney disease called chronic kidney disease-mineral bone disorder (CKD-MBD) may increase your risk for severe low calcium levels in blood. Before you start PONLIMSI and during treatment, your doctor may need to do certain blood tests to check for CKD-MBD.

If you have advanced chronic kidney disease, your doctor may coordinate your PONLIMSI treatment with a healthcare provider with expertise in CKD-MBD.

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