MEDICATION GUIDE

PONLIMSI™ (pon-LIM-see)

(denosumab-adet)

injection, for subcutaneous use

What is the most important information I should know about PONLIMSI?

If you receive PONLIMSI, you should not receive other denosumab products at the same time.

PONLIMSI can cause serious side effects including:

- **Increased risk of severe low calcium levels in your blood (hypocalcemia).** PONLIMSI may lower the calcium levels in your blood. 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. Talk to your doctor before starting 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, which could result in 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.

  Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away 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

- **Serious allergic reactions.** Serious allergic reactions have happened in people who take denosumab products. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction. Symptoms of a serious allergic reaction may include:
  - low blood pressure (hypotension)
  - trouble breathing
  - throat tightness
  - swelling of your face, lips, or tongue
  - rash
  - itching
  - hives
- **Severe jaw bone problems (osteonecrosis).** Severe jaw bone problems may happen when you take PONLIMSI. Your doctor should examine your mouth before you start PONLIMSI. Your doctor may tell you to see your dentist before you start PONLIMSI. It is important for you to practice good mouth care during treatment with PONLIMSI. Ask your doctor or dentist about good mouth care if you have any questions.
- **Unusual thigh bone fractures.** Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture include new or unusual pain in your hip, groin, or thigh.
- **Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying PONLIMSI.** Talk with your doctor before starting PONLIMSI treatment. After your treatment with PONLIMSI is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Your risk for having more than 1 broken bone in your spine is increased if you have already had a broken bone in your spine. Do not stop, skip or delay taking PONLIMSI without first talking with your doctor. If your PONLIMSI treatment is stopped, talk to your doctor about other medicine that you can take.
- **Serious infections.** Serious infections in your skin, lower stomach area (abdomen), bladder, or ear may

happen if you take PONLIMSI. Inflammation of the inner lining of the heart (endocarditis) due to an infection also may happen more often in people who take PONLIMSI. You may need to go to the hospital for treatment if you develop an infection.
PONLIMSI is a medicine that may affect the ability of your body to fight infections. People who have a weakened immune system or take medicines that affect the immune system may have an increased risk for developing serious infections. Call your doctor right away if you have any of the following symptoms of infection:

- fever or chills
- skin that looks red or swollen and is hot or tender to touch
- fever, shortness of breath, cough that will not go away
- severe abdominal pain
- frequent or urgent need to urinate or burning feeling when you urinate

- **Skin problems.** Skin problems such as inflammation of your skin (dermatitis), rash, and eczema may happen if you take PONLIMSI. Call your doctor if you have any of the following symptoms of skin problems that do not go away or get worse:
  - redness
  - itching
  - small bumps or patches (rash)
  - your skin is dry or feels like leather
  - blisters that ooze or become crusty
  - skin peeling
- **Bone, joint, or muscle pain.** Some people who take denosumab products develop severe bone, joint, or muscle pain.

Call your doctor right away if you have any of these side effects.

What is PONLIMSI?

PONLIMSI 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 osteoporosis in men and women who will be taking corticosteroid medicines (such as prednisone) for at least 6 months and 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.

It is not known if PONLIMSI is safe and effective in children. PONLIMSI is not approved for use in children.

Do not take PONLIMSI if you:

- have been told by your doctor that your blood calcium level is too low.
- are pregnant or plan to become pregnant.
- are allergic to denosumab products or any of the ingredients in PONLIMSI. See the end of this Medication Guide for a complete list of ingredients in PONLIMSI.

Before taking PONLIMSI, tell your doctor about all of your medical conditions, including if you:

- are taking other denosumab products.
- have low blood calcium.
- cannot take daily calcium and vitamin D.
- had parathyroid or thyroid surgery (glands located in your neck).
- have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome).

- have kidney problems or are on kidney dialysis.
- are taking medicine that can lower your blood calcium levels.
- plan to have dental surgery or teeth removed.
- are pregnant or plan to become pregnant. PONLIMSI may harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with PONLIMSI.
  - You should use an effective method of birth control (contraception) during treatment with PONLIMSI and for at least 5 months after your last dose of PONLIMSI.
  - Tell your doctor right away if you become pregnant while taking PONLIMSI.
- are breastfeeding or plan to breastfeed. It is not known if PONLIMSI passes into your breast milk. You and your doctor should decide if you will take PONLIMSI or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of medicines with you to show to your doctor or pharmacist when you get a new medicine.

How will I receive PONLIMSI?

- PONLIMSI is an injection that will be given to you by a healthcare provider. PONLIMSI is injected under your skin (subcutaneous).
- You will receive PONLIMSI 1 time every 6 months.
- You should take calcium and vitamin D as your doctor tells you to while you receive PONLIMSI.
- If you miss a dose of PONLIMSI, you should receive your injection as soon as you can.
- Take good care of your teeth and gums while you receive PONLIMSI. Brush and floss your teeth regularly.
- Tell your dentist that you are receiving PONLIMSI before you have dental work.

What are the possible side effects of PONLIMSI?

PONLIMSI may cause serious side effects.

- See **"What is the most important information I should know about PONLIMSI?"**
- It is not known if the use of PONLIMSI over a long period of time may cause slow healing of broken bones.

The most common side effects of PONLIMSI in women who are being treated for osteoporosis after menopause are:

- back pain
- pain in your arms and legs
- high cholesterol
- muscle pain
- bladder infection

The most common side effects of PONLIMSI in men with osteoporosis are:

- back pain
- joint pain
- common cold (runny nose or sore throat)

The most common side effects of PONLIMSI in patients with glucocorticoid-induced osteoporosis are:

- back pain
- high blood pressure
- lung infection (bronchitis)
- headache

The most common side effects of PONLIMSI in patients receiving certain treatments for prostate or breast cancer are:

- joint pain
- back pain
- pain in your arms and legs
- muscle pain

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of PONLIMSI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PONLIMSI if I need to pick it up from a pharmacy?

- Keep PONLIMSI refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton.
- Do not freeze PONLIMSI.
- When you remove PONLIMSI from the refrigerator, PONLIMSI must be kept at room temperature [up to 86°F (30°C)] in the original carton and must be used within 32 days.
- Do not keep PONLIMSI at temperatures above 86°F (30°C). Warm temperatures will affect how PONLIMSI works.
- Do not shake PONLIMSI.
- Keep PONLIMSI in the original carton to protect from light.

Keep PONLIMSI and all medicines out of the reach of children.

General information about the safe and effective use of PONLIMSI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PONLIMSI for a condition for which it was not prescribed. Do not give PONLIMSI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about PONLIMSI that is written for healthcare providers.

What are the ingredients in PONLIMSI?

Active ingredient: denosumab-adet

Inactive ingredients: glacial acetic acid, polysorbate 20, sodium acetate, sorbitol, water for injection

Manufactured By: Teva Pharmaceuticals, Inc., Parsippany, NJ 07054
U.S. License No: 2325

Product of Germany
For more information, go to www.PONLIMSI.com or call Teva at 1-888-483-8279.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 03/2026