



## **EVENITY™ (ROMOSUZUMAB) INFORMED CONSENT FORM**

Your physician has recommended an EVENITY™ Injection for the treatment of osteoporosis. Before agreeing to this treatment, it is important that you read and understand the following explanation of the EVENITY™ Injection Treatment Process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

### **Indications**

EVENITY™ (romosozumab-aqqp) INJECTION FOR OSTEOPOROSIS indicated for:

The treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

### **Limitations of Use**

The anabolic effect EVENITY™ wanes after 12 monthly doses of therapy. Therefore, the duration of therapy should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

### **Dosage and Administration**

The recommended dose of EVENITY™ is as follows:

Two separate syringes (and two separate subcutaneous injections) are needed to administer the total dose of 210 mg of EVENITY™. Inject two 105 mg/1.17 mL prefilled syringes, one after the other. EVENITY™ should be administered by a healthcare provider.

Patients receiving EVENITY™ should continue to take calcium and vitamin D. Calcium and vitamin D intake is important in women with osteoporosis and the current recommended daily intake of calcium is 1,200 mg and vitamin D is 400-800 IU daily.

Potential adverse reactions, all of which are uncommon, include:

- Bone, joint or muscle pain
- Constant jaw pain, including burning or cramping
- Eye inflammation, pain, or vision change
- Impairment of kidney function - very uncommon unless baseline kidney function is abnormal.
- Low blood calcium level - everyone taking EVENITY should be receiving calcium and vitamin D supplements to minimize this risk unless contraindicated.
- Allergic reaction
- Osteonecrosis of the jaw - if you have oral pain, loosening of the teeth, or an infection of the mouth that will not heal, please alert your doctor.

- EVENITY has a black box warning for myocardial infarction

Prior to using EVENITY, please tell your physician or nurse if you (please initial):

- \_\_\_\_\_ History of a heart attack or stroke within the last year
- \_\_\_\_\_ Kidney problems
- \_\_\_\_\_ History of low blood calcium level
- \_\_\_\_\_ Pregnant or breast feeding
- \_\_\_\_\_ Not able to take daily calcium and vitamin D supplements
- \_\_\_\_\_ Parathyroid or thyroid surgery
- \_\_\_\_\_ Malabsorption syndrome
- \_\_\_\_\_ Section of your intestine removed
- \_\_\_\_\_ Planned dental surgery
- \_\_\_\_\_ Any Fever or Current Signs/Symptoms of an Infection
- \_\_\_\_\_ Any Acute Cut, Wound or Rash

I understand all possible side effects from this medication may not have been completely identified and as new information becomes available I will be notified.

I have had the opportunity to fully read, understand and discuss this consent form with my physician and the nurses. By signing this consent, I am agreeing to treatment with EVENITY.

\_\_\_\_\_  
Patient's Name

\_\_\_\_\_  
Witness' Name

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date