

## INFORMED CONSENT FOR TREATMENT WITH RECLAST/ZOLEDRONIC ACID

Reclast (Zoledronic Acid) is FDA approved for the treatment of postmenopausal osteoporosis and Paget's disease. Osteoporosis is a disease that causes weakening of bone and an increased risk of bone fractures. Paget's disease is a disorder of bone metabolism. Reclast is a bisphosphonate medication in the same class as Fosamax, Actonel and Boniva. These medications work by reducing the rate bone is reabsorbed so that the body can start to build back bone strength. Your doctor is prescribing this medication either because you have low bone density or because you are taking medication(s) that could cause low bone density or to treat Paget's disease.

### CONTRAINDICATIONS:

#### Hypocalcemia (Low blood calcium)

Reclast should not be taken by patients who have low calcium levels or recent surgery on the thyroid or parathyroid glands, because the medication may lower calcium levels further. Your doctor will check your calcium by a blood test before each infusion of Reclast. Patients with Paget's disease have a higher risk of hypocalcemia. If you have Paget's disease, ask your doctor about the symptoms of hypocalcemia before you have your first infusion and notify your doctor promptly if these symptoms occur. All post-menopausal women treated with Reclast should also be taking both calcium and vitamin D daily.

#### Allergic Reactions

There have been rare cases of allergic reactions to Reclast resulting in hives, difficulty breathing and even anaphylactic reactions. You should not take this medication if you have had an allergic reaction to either Reclast.

### WARNINGS AND PRECAUTIONS:

#### Kidney Problems

There have been reports of patients developing decreased kidney function after infusion with Reclast. This is more likely to occur in people with certain pre-existing kidney problems. Notify your doctor if you have a known kidney problem so he/she can order additional testing if necessary. Your doctor will check your kidney function via a blood test prior to your Reclast infusion.

#### Osteonecrosis of the Jaw

Osteonecrosis of the jaw has occurred in a small percentage of patients taking bisphosphonate medications (including Reclast, Zometa, Fosamax, Actonel and Boniva). This is a painful condition affecting the jaw bones. Most cases have occurred in cancer patients treated with intravenous bisphosphonates who have undergone dental procedures. Some cases of osteonecrosis of the jaw have occurred in patients taking these medications for osteoporosis. If you have a planned dental procedure, be sure to discuss this with your doctor prior to starting Reclast. It is recommended to receive a routine dental examination prior to treatment.

#### Musculoskeletal Pain

Severe muscle, joint and/or bone pain have occurred infrequently in patients after treatment with Reclast.

### Aspirin Sensitive Patients

There have been reports of asthma-like reactions in Aspirin-sensitive patients treated with bisphosphonate medications.

### Pregnancy

Reclast **SHOULD NOT BE USED IN WOMEN WHO ARE PREGNANT OR MAY BECOME PREGNANT** as it may cause harm to the fetus. Reclast should not be used in nursing women or in children as their effects are unknown.

### **ADVERSE REACTIONS:**

The most common side effects of Reclast in clinical trials were headaches, fever, joint or muscle pain and elevated blood pressure. In addition, some patients experienced gastrointestinal symptoms including nausea, diarrhea, constipation, abdominal pain, bloating or vomiting after their Reclast infusion. Flu-like symptoms, chills, fatigue, decreased appetite, and dizziness have also been observed in some patients.

### **DRUG INTERACTIONS:**

Tell your doctor if you are on any antibiotics or a diuretic (water pill) because there may be an interaction between these medications and Reclast that could seriously lower your body's calcium level.

### **MEDICATION ADMINISTRATION:**

Reclast is given as an intravenous infusion typically lasting at least 15 minutes, in the office once per year. If you are on water pills, please do not take them on the morning of your infusion.

### **EMERGENCY CONTACTS:**

In case of an emergency, please call 911 or go to the nearest emergency room. You can contact our office at (916)677-4744 from 8:00 am to 5:00 pm Monday – Friday.

I certify that I have read and understand this consent form and agree to receive Reclast infusion. I have had an opportunity to discuss this treatment, its risks, benefits and alternatives with my physician and have had all my questions answered to my satisfaction.

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Patient DOB

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

### **FINANCIAL RESPONSIBILITY:**

Our office will contact your insurance company, and the necessary arrangements will be made for approval of the medication and administration. You may want to follow up with your insurance company also to be sure everything is covered. **Our office does NOT provide a guarantee of coverage for any of these services. If coverage is not provided, YOU WILL BE RESPONSIBLE for any charges incurred for treatment and/or follow-up care.**

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date