



## ORENCIA INFORMED CONSENT FORM

Your physician has recommended an ORENCIA infusion for your treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the ORENCIA infusion process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

ORENCIA is a medication that keeps the immune system from attacking healthy tissues in the body. The immune system also defends the body against infections caused by bacteria and viruses. ORENCIA interferes with an important step in this attack. By decreasing the immune system's attack on normal tissues, ORENCIA can reduce pain and joint inflammation, and can slow the damage to your bones and cartilage.

### Indications

ORENCIA is indicated and FDA approved for rheumatoid arthritis and psoriatic arthritis.

### Dosage and Administration

ORENCIA is administered by intravenous infusion that will last about 30 minutes. One should allow sufficient time for pre and post infusion evaluation. We will place an IV in your arm, which may be uncomfortable. You will receive your first dose of ORENCIA followed by additional doses at 2 and 4 weeks. You will then receive a dose every 4 weeks. Ask your doctor if you miss an infusion when to schedule your next dose.

A full clinical response may not be evident for several weeks following the infusion. You should continue to take all of your other medications, unless otherwise indicated by your physician.

### Potential Adverse Reactions

ORENCIA is generally well tolerated and most reported reactions are mild to moderate, transient and manageable. The following adverse reactions are the most commonly reported:

- Upper respiratory infection
- Viral infection
- Bronchitis
- Flushing
- Rash

Some more severe side effects have been reported including:

- Serious infection
- Allergic reactions. These reactions are usually mild or moderate, but can be severe.
- There have been rare cases of certain kinds of cancer in patients receiving ORENCIA. The role of

ORENCIA in the development of cancer is not known.

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

- \_\_\_\_\_ Have been previously exposed to tuberculosis (TB)
- \_\_\_\_\_ Have has Hepatitis B or C Infection
- \_\_\_\_\_ Pregnant or breast feeding
- \_\_\_\_\_ Have new symptoms or medical problems
- \_\_\_\_\_ Have had any live vaccinations recently (These include measles, mumps, rubella, oral polio (the injectable polio vaccine is not live), oral typhoid (typhoid injection is not live), BCG, yellow fever)
- \_\_\_\_\_ 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 ORENCIA.

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

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

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

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date