



BENLYSTA INFORMED CONSENT FORM

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

BENLYSTA 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. BENLYSTA interferes with an important step in this attack. By decreasing the immune system's attack on normal tissues.

Indications

BENLYSTA is indicated and FDA approved for systemic lupus erythematosus that does not affect the kidneys.

Dosage and Administration

BENLYSTA will be given to you by a health care professional using an IV. This means that the medicine will be given to you through a needle placed in a vein in your arm. It will take about 60 minutes for the full dose of medicine.

You will receive your BENLYSTA at two week intervals for the first 3 doses and at 4 week intervals thereafter. 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

BENLYSTA 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
- Headache
- Diarrhea
- Decreased white count
- Nausea and vomiting

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 BENLYSTA. The role of BENLYSTA in the development of cancer is not known.
- A **rare** and serious brain infection called progressive multifocal leukoencephalopathy (PML) caused by the JC virus has occurred in patients having received immunosuppressants, including BENLYSTA.

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

- _____ Have been previously exposed to tuberculosis (TB)
- _____ Have has Hepatitis B or C Infection
- _____ Have any type of cancer
- _____ 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 BENLYSTA.

Patient's Name

Witness' Name

Patient's Signature

Witness' Signature

Date

Date