

## INFORMED CONSENT FOR TREATMENT WITH INTRAVENOUS COSENTYX

Cosentyx has been approved by the Food and Drug Administration (FDA) for the treatment of Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, and Hidradenitis Suppurativa. Cosentyx blocks the action of Interleukin 17A Receptor. Treatment with Cosentyx results in decreased swelling, inflammation, and decreased immune system (immunosuppression) since swelling and overactive immune system probably play a role in the above-mentioned diseases.

### WARNINGS:

Cosentyx causes suppression of the immune system which can result in serious infections including invasive fungal infections or worsening of an existing infection. A higher rate of infections including nasopharyngitis, upper respiratory infections and mucocutaneous candida were reported in clinical trials. Before starting treatment with Cosentyx you should have a tuberculosis skin test (PPD) done to check for tuberculosis that may not be causing any symptoms (latent tuberculosis). If you have been diagnosed with tuberculosis, anti-tuberculosis medicines must be started before you start Cosentyx. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis or have been in contact with someone with tuberculosis. Tell your doctor if you have ever had a positive PPD as this may require treatment. Tell your doctor immediately if you have any complaints that may indicate an infection. These include but are not limited to pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus. Tell your doctor if you have been diagnosed with an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive Cosentyx while you have an infection or while you are on antibiotics. Cosentyx can restart once you have completed your antibiotic course, and your infection has been resolved. Tell your doctor if you have planned surgery, as you will need to stop your Cosentyx temporarily around the time of your surgery. Please confirm with your doctor about when to stop and restart Cosentyx before and after surgery.

### PRECAUTIONS:

Treatment with Cosentyx may cause exacerbations and new onset of inflammatory bowel disease. Please talk to your doctor if you get new GI symptoms/ blood in stools. Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to developing cancer, in particular lymphoma. The impact of Cosentyx on this is not known. Possible long-term side effects such as the development of lymphoma or other cancers cannot be predicted. It is not known if Cosentyx can cause fetal harm when given during pregnancy, or if it is safe to receive Cosentyx while breast feeding. Some dosage forms may contain dry natural rubber (latex). Please let your physician know if you have a known latex allergy. You should NOT receive live vaccines (for e.g. polio, smallpox, nasal spray flu or live shingles vaccine) while on Cosentyx. The injected flu vaccine, pneumonia vaccines and injectable killed shingles vaccines can be safely administered while on Cosentyx. Please let your doctor know if someone in your household has received or will receive a live virus vaccine.

### ADVERSE REACTIONS:

The most common side effect from Cosentyx is a reaction at the site of IV, redness, itching or hives. If a reaction occurs it is usually mild and goes away after a few weeks of continued usage of the drug. Other side effects include but are not limited to upper respiratory infections such as sinus infections, headache and nausea.

**ALLERGIC REACTIONS:**

In rare cases severe allergic reactions may occur, leading to difficulty breathing and low blood pressure or shock. Allergic reactions can happen after your first dose or may not happen until after you have taken Cosentyx many times. If you develop a severe rash, swollen face or difficulty breathing while taking Cosentyx, call your doctor right away or seek emergency care immediately.

**MEDICATION ADMINISTRATION:**

IV Cosentyx is a quick 30-minute infusion from start to finish and it is given every 4 weeks.

**EMERGENCY CONTACTS:**

In case of emergency, 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 understood this consent form and agree to receive IV Cosentyx. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

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

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