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INFORMED CONSENT FOR TREATMENT WITH COSENTYX OR TALTZ

Cosentyx has been approved by the Food and Drug Administration (FDA) for the treatment of Plaque Psoriasis, Psoriatic Arthritis and Ankylosing Spondylitis. Taltz has been approved by the Food and Drug Administration (FDA) for the treatment of Plaque Psoriasis, Psoriatic Arthritis and Ankylosing Spondylitis.
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Cosentyx and Taltz block the action of Interleukin 17A Receptor. This blockade results in decreased swelling (inflammation) and decreased immune system function (immunosuppression). Cosentyx and Taltz are effective in treating the above diseases since swelling and an overactive immune system probably play a role in these diseases.

WARNINGS:

Cosentyx and Taltz decrease immune system function (immunosuppression), 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 muco-cutaneous candida was reported in clinical trials.

Before starting treatment with Cosentyx or Taltz you should have a tuberculosis skin test 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 Cosentyxor Taltz therapy. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis or have come in contact with someone with tuberculosis. Tell your doctor if you have ever had a positive PPD (tuberculosis skin test) – 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 as having an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive Cosentyx or Taltz while you have an infection or while you are on antibiotics. Cosentyx or Taltz can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop your Cosentyx or Taltz temporarily around the time of your surgery.

PRECAUTIONS:

Treatment with Cosentyx or Taltz 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 develop cancer, in particular lymphoma. The impact of Cosentyx or Taltz 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 or Taltz can cause fetal harm when given during pregnancy, or if it is safe to receive Cosentyx or Taltz 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 eg. polio, smallpox, nasal spray flu or live shingles vaccine) while on Cosentyx or Taltz. The injected flu vaccine, pneumonia vaccines and injectable killed shingles vaccines can be safely administered while on Cosentyx or Taltz. 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 or Taltz is a reaction at the site of the injection. You may experience some 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 or Taltz many times. If you develop a severe rash, swollen face or difficulty breathing while taking Cosentyx or Taltz, call your doctor right away or seek emergency care immediately.

MEDICATION ADMINISTRATION:

Cosentyx is injected under the skin weekly for 5 doses and then every 4 weeks. Cosentyx may also be given without loading dose (under the skin) every 4 weeks. Taltz is self-injected with a loading dose of 2 injections at week 0, one injection at weeks 2,4,6,8,10 and 12, and then with a maintenance dose of 1 injection every 4 weeks. You will be taught how to do the injections.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive and self administer 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.

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Patient signature DOB

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Date