

BIOLOGIC THERAPY - PATIENT CONSENT

(adalimumab, etanercept, infliximab, ustekinumab)
IMPORTANT TREATMENT CONSIDERATIONS

Biologic Therapy (adalimumab, etanercept, infliximab, ustekinumab) is indicated for the treatment of adult patients with chronic moderate to severe plaque psoriasis who are not candidates for systemic therapy or phototherapy.

Biologic Therapy (BT) is also indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). BT can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

BT is indicated for reducing the signs and symptoms and inhibiting the progression of structural damage of active arthritis in patients with psoriatic arthritis.

Since the product was first introduced, the following have been reported in patients using BT:

- **SERIOUS INFECTIONS**

- Many occurred in people prone to infection, such as those with advanced or poorly controlled diabetes.
- Some serious infections were fatal.
- Rare cases of new tuberculosis or activation of dormant tuberculosis
- Increased rates of infection have been reported.
- Upper respiratory infections are the most common infections reported.

- **MAJOR CARDIAC EVENTS**

- Recent early studies suggest up to a 1 in 300 risk of heart attack, stroke or sudden death. More research is pending.

- **WHAT TO DO/NOT DO**

- Do not start BT if you have an infection or are allergic to BT or its components.
 - Tell your doctor if you are prone to infection.
 - Stop BT if a serious infection occurs.
 - Contact your doctor if you have questions about BT or develop an infection.
 - Do not use BT if you have anemia or blood abnormalities.
 - Do not receive injections of live vaccines while taking BT.
 - Tell your doctor if you are being treated for heart failure.
 - Tell your doctor if you have or have had TB, hepatitis, AIDS or internal fungal infections.
 - Tell your doctor if you have been vaccinated (BCG) against TB or hepatitis.
- Serious nervous system disorders such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes.
 - Tell your doctor if you have ever had any of these disorders or if you develop them after starting BT.
 - Rare reports of serious blood disorders (some fatal).
 - **Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding or paleness.**
 - In medical studies of all TNF and T-cell inhibitors, a higher rate of lymphoma (a type of cancer) and leukemia was seen compared to the general population, however, the risk of these disorders may be up to several-fold higher in RA and psoriasis patients.
 - The role of these inhibitors in the development of such disorders is unknown.
 - The incidence of other cancers has not increased with exposure to Biologic Therapy and is similar to the expected rate.
 - Biologics can also cause injection site reactions.

If you have any questions about this information, be sure to discuss them with us.

I have read and understand the preceding information.

Patient or Guardian Signature

Date

02/10 #49 _____

Nurse Initials