

# Enbrel (etanercept) Flowsheet

**Indications:** \_\_\_ Severe plaque psoriasis in adults ( $\geq 18$  years)  
 \_\_\_ Psoriatic arthritis \_\_\_ JRA not responding to one or more DMARD  
 \_\_\_ RA \_\_\_ ankylosing spondylitis

**Off-label use:** \_\_\_ psoriasis \_\_\_ other \_\_\_\_\_

**Contraindications:** \_\_\_ hypersensitivity  
 \_\_\_ sepsis, active infection (chronic or localized) or hx of recurrent infections

**Precautions in:** \_\_\_ seizure disorders  
 \_\_\_ hx of blood dyscrasias  
 \_\_\_ transverse myelitis, optic neuritis, MS or other demyelinating disorder  
 \_\_\_ hx of CHF  
 \_\_\_ elderly (increased risk of infections)  
 \_\_\_ pregnancy (Cat B) or breastfeeding (unknown)  
 \_\_\_ significant exposure to varicella zoster virus (stop tx and consider VZIG)  
 \_\_\_ advanced or uncontrolled diabetes or other immunosuppressive disease

**DOSE:** 50mg S.Q. 2 times/week, 3-4 days apart (plaque psoriasis)  
 25mg S.Q. 2 times/week, 3-4 days apart (psoriatic arthritis)

**RX:** 4 cartons of 4 dose trays each (a one month supply for plaque psoriasis).  
 1 carton = 4 dose trays. 1 dose tray has a 25mg vial of Enbrel and injection supplies.

**Monitoring\***

	<u>Baseline</u>	<u>1 mo</u>	<u>2 mos</u>	<u>3 mos</u>	<u>4 mos</u>	<u>5 mos</u>	<u>6 mos</u>
HCG	___						
CBC**	___	___		___			___
ANA***	___			___			___
IPPD	___						
Neuro Exam****	___						
PASI	___	___	___	___	___	___	___

\*In package insert, no monitoring is listed as required, however case reports and prudence would suggest listed monitoring.

\*\*Rare cases of pancytopenia including aplastic anemia, some with fatal outcome, have been reported with Enbrel. Causal relationship is unclear.

\*\*\*ANA became positive in 11% of pts in studies. Anti-dsDNA became positive in 15% of pts. Long-term relationship to developing autoimmune diseases is unknown.

\*\*\*\*Rare cases of new onset or exacerbation of CNS demyelinating disorders, some presenting with mental status changes. Increases of MS disease activity have been reported. Causal relationship to Enbrel is unclear.

# Enbrel (etanercept) Info (for physicians)

**What it is:** a dimeric fusion protein – TNF receptor attached to human IgG.

**How produced:** recombinant DNA technology in a Chinese hamster ovary mammalian cell expression system.

**Works by:** binding to TNF (both alpha and beta). TNF is increased in lesions of psoriasis compared to normal skin.

**What to expect:** Decreased itching and feeling better within days.

**Plaque psoriasis using the 50mg BIW dose:**

3 months: 46- 47% - PASI 75% (43% more than placebo group)

71-72% - PASI 50% (57-64% more than placebo group)

6 months: 54% - PASI 75%

**Note:** Pts with erythroderma, pustular or guttate psoriasis were excluded in studies.

**Psoriatic arthritis:** clinical response w/in 4 weeks.

ACR 20/50/70 response in 50%, 37% and 9% respectively, at 6 months.

**Half-life:** 115hrs

**Hepatic or renal impairment:** no studies done.

**Interactions:** No studies done.

Insert says it can be used with methotrexate, however insert also says there is an increased risk of serious infections when used with other immunosuppressants.

**Carcinogenesis or impairment of fertility:** no studies done.

**Pregnancy Cat. B**

**Not mutagenic**

**Reconstitution:** Dose tray: 25mg vial of Enbrel

One syringe with 1ml of bacteriostatic water for injection

One plunger and vial adaptor

Two alcohol swabs

Dating sticker for vial (prob. not needed if used right away)

27g ½ inch needle

Reconstituted solution is good for 14 days. Keep refrigerated at all times. Don't freeze.

## Psoriatic Arthritis Info

	<u>PsA</u>	<u>RA</u>
Male: Female	1:1	1:3
Enthesopathy	Y	N
Joints	few	many
Skin Disease	almost always	unusual
RF	neg	pos
Axial disease (spine, sacrum)	20-30%	uncommon
Bowel Inflammation	yes ( <i>subclinical</i> )	no

**Characteristic features:** fingernail dystrophy, DIP involvement, asymmetry, few joints, dactylitis.

80-85% will have skin disease preceding by months or years. Diagnosis is clinical.

**X-ray findings:** osteolysis, fibrosis, new bone formation, arthritis of spine and sacrum.

**Treatment:** methotrexate or cyclosporine are most commonly used agents. Steroids- controversial.

Some NSAIDS can make worse. Enbrel is approved for PsA.

# **Enbrel (etanercept) Consent Form**

All medicines have side effects and Enbrel is no different. Before using Enbrel, it is important that you be made aware of certain side effects.

## **Enbrel may cause:**

### **Initials**

\_\_\_\_\_ 1. Increased risk of infections. The most common type of infections were mild upper respiratory types of infection. There have been rare cases where patients taking Enbrel have developed serious infections, including tuberculosis (TB) and infections caused by bacteria or fungi that have spread throughout their body (sepsis). Some patients have died from these infections. If you get infections easily or if you develop an infection while taking Enbrel, you should tell your doctor right away.

\_\_\_\_\_ 2. Injection site reaction. These occur in 30 – 40% of patients, are typically mild to moderate (redness, itching, pain, swelling) and do not necessitate discontinuation of therapy. These reactions typically last for 3-5 days and decrease in frequency with continued treatment. If you have pain, redness or swelling around the injection site that does not go away or gets worse, call your doctor.

\_\_\_\_\_ 4. Allergic reactions (<2% of patients). If you develop a severe rash, swollen face or difficulty breathing while taking Enbrel, call your doctor right away or go to the emergency room.

\_\_\_\_\_ 5. Nervous system diseases. There have been rare cases of disorders that affect the nervous system of people taking Enbrel. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling throughout your body, problems with your vision, weakness in your arms and/or legs and dizziness. Whether Enbrel caused these disorders is unclear.

\_\_\_\_\_ 6. Blood problems. In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop your treatment. Some people have also had symptoms that resemble lupus (rash on face and arms that gets worse in sun) that may go away when you stop taking Enbrel.

\_\_\_\_\_ 7. Lymphoma (a type of cancer) occurs in greater frequency in patients with rheumatoid arthritis than in the general population. Since Enbrel has been studied in patients with rheumatoid arthritis, Enbrel has also been reportedly associated with an increased incidence of lymphomas. The increased rate was not greater than would be expected in patients with rheumatoid arthritis. There have been rare reports of lymphoma in patients taking Enbrel occurring more often than expected for people in general. The role of Enbrel in the development of cancer is not known.

\_\_\_\_\_ 8. Heart problems. You should tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on Enbrel, or may want to monitor you more closely.

\_\_\_\_\_ 9. I understand I should not take Enbrel if I am pregnant, trying to get pregnant or breastfeeding. I should use two effective methods of birth control while taking Enbrel. If I do not understand what two effective methods of birth control entails, I will see an OB/GYN physician for appropriate counseling before starting Enbrel.

\_\_\_\_\_ 10. I understand I should not receive live virus vaccines while taking Enbrel, and other vaccines may be less effective.

\_\_\_\_\_ 11. I understand exposure to someone with chicken pox or shingles (herpes zoster) is very dangerous while taking Enbrel and I should report any exposure to my physician immediately.

\_\_\_\_\_ 12. I understand I should report to my doctor immediately if I develop a persistent fever, bruising, bleeding or pallor (become pale appearing).

\_\_\_\_\_ 13. I understand that Enbrel is an injection type of therapy that I, or someone else properly trained, must give.

\_\_\_\_\_ 14. Tell your doctor if you have any kind of infection including an infection that is only in one place (such as an open sore), or an infection that is in your whole body (such as the flu), a history of infections that keep coming back or other conditions like diabetes, that might increase your risk of infections.

\_\_\_\_\_ 15. Notify your doctor if you have ever had a positive test for tuberculosis (TB), or if you have been or will be in close contact with someone who has had, or has tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. You will need to be examined for TB and have a skin test or chest x-ray.

\_\_\_\_\_ 16. Notify your doctor if you have been scheduled for major surgery or have been scheduled to be vaccinated for anything.

\_\_\_\_\_ 17. I understand that this is a partial list of possible side effects and a more complete listing can be found in the package insert available from the pharmacist. I also understand that since Enbrel is a relatively new drug on the market, there may be side effects that we do not know about and sometimes are not discovered until much later.

I have read the above 17 items, have had the opportunity to ask any questions and received answers to my satisfaction. I have also had alternative treatments explained to me, including doing nothing. I hereby consent to be treated with Enbrel.

\_\_\_\_\_

Name and Signature

\_\_\_\_\_

Date

\_\_\_\_\_

Physician Name and Signature

\_\_\_\_\_

Date

\_\_\_\_\_

Witness Name and Signature

\_\_\_\_\_

Date

## PASI Score

	Surface area*	% in patient	<u>Totals</u>	*use these numbers for surface area
1. Head			Head = _____	0 = none
2. Ant Upper Trunk				1 = <10%
3. Ant Lower Trunk			Trunk: 2 + 3 +4 + 5 = _____	2 = 10-20%
4. Post Upper Trunk				3 = 30-49%
5. Post Lower Trunk				4 = 50-69%
6. Legs			Legs (LE) = _____	5 = 70-80%
7. Arms			Arms (LE) = _____	6 = 90-100%

**Step #1:** Determine **surface area score** (use scoring in **column on right**). Put **totals** in #5 below.

**Step #2:** Assign a score for the erythema, induration and scaling below, then add in row #4

**Step #3:** Calculate each column of #7.

**Step #4:** Calculate **PASI score** by adding numbers on row #7.

Score for erythema, induration and scaling : 0 = none  
 1 = slight  
 2 = moderate  
 3 = severe  
 4 = extraordinarily severe

### PASI Score:

	Head	UE	Trunk	LE	
1. Erythema					
2. Induration					
3. Scaling					
4. Sum of 1,2,3					
5. Area totals					
6. Area weights	0.1	0.2	0.3	0.4	
7. 4 x 5 x 6		+	+	+	= <b style="color: blue;">PASI SCORE:</b>