Patient Card

This Card contains important safety information that you need to be aware of before you are given Etanercept and during treatment with Etanercept.
If you do not understand this information, please ask your doctor to explain it to you.

- Show this card to any doctor involved in your treatment.
- See the Etanercept package leaflet for more information.
- Keep this card with you for 2 months after the Etanercept dose, since side effects may occur after your last dose of Etanercept.

Infections

Etanercept may increase the risk of getting infections, which could be serious.
• You should not use Etanercept if you have an infection. If you are not sure, ask your doctor.

• If you develop symptoms suggestive of infection, such as fever, persistent cough, weight loss or listlessness, seek medical attention immediately.

• You should be evaluated for tuberculosis (TB). Ask your doctor to record the dates and results of your last screening for TB below:

Test:_____
Date:_____
Results:_____

Test:_____
Date:_____
Results:_____

Please ask your doctor to list your other medications that may increase your risk of infection.

_____ _____

_____ _____

_____ _____

Congestive Heart Failure

If you develop symptoms suggestive of congestive heart failure or worsening of existing congestive heart failure such as shortness of breath, swelling of ankles, persistent cough or fatigue, seek medical attention immediately.

Other information (please complete):
• Patient's name: _____
• Doctor's name: _____
• Doctor's phone number: _____

It is important that you and your doctor record the brand name and batch number of your medication.

Brand Name: _____

Batch Number: _____

Call for reporting

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,

Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt

Healthcare Professionals may also report any adverse events associated with the use of ERELZI to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com

Marketing Authorization Holder: Sandoz GmbH Biochemiestr. 10 A-6250 Kundl Austria

Local Distributor: V.J. Salomone Pharma Limited - Upper Cross Road, Marsa, MRS 1542, Malta.

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm- and download the required material with the latest date.

This educational material is a part of the conditions of the Marketing Authorization"