

**Patient Safety
Information Card
Brenzys 50 mg/ml
Etanercept**

This card contains important safety information that you need to be aware of before you are given Brenzys and during treatment with Brenzys 50 mg/ml. 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 or your child's treatment.

Use in children and adolescents

Brenzys 50 mg/ml is not indicated for use in children and adolescents weighing less than 62.5 kg. Please ask your doctor if you have any questions about this.

Infections

Brenzys 50 mg/ml may increase your risk of getting infections, which could be serious.

- You should not use Brenzys 50 mg/ml if you have an infection. If you are not sure, ask your doctor.
- If you develop symptoms suggestive of infections, such as fever, persistent cough, shortness of breath, chills, weakness or weight loss, seek medical attention immediately.
- You should be referred by your doctor for evaluation and diagnosis of tuberculosis prior to the treatment initiation and during the treatment if needed. Ask your doctor to record the dates and the results of your last screening for TB below:

Test: _____ Test: _____

Date: _____ Date: _____

Results: _____ Results: _____

- Please inform your doctor if you are intended to be vaccinated. There are vaccinations you should not get during the treatment.
- Please inform your doctor if you receive or recently received other medicines, including non-prescription medicines and nutritional supplements.
- Please ask your doctor to list your other medicines that may increase your risk of infection.

Congestive heart failure

- If you have congestive heart failure, and you think your symptoms (e.g., shortness of breath, cough, tiredness or swelling of the feet or in the abdomen) are becoming worse, or you experience new onset of such symptoms, seek medical attention immediately.

Malignancies

- If you have or have had cancer, please tell your doctor. Periodic dermatological examination is recommended. In addition, you should refer to the doctor in case you observe any changes in your skin.

Other information (please complete)

Patient's name: _____

Doctor's name: _____

Doctor's phone: _____

- Keep this card with you for 2 months after the last Brenzys 50 mg/ml dose, since side effects may occur after your last dose of Brenzys 50 mg/ml.

Adverse events reporting

Reporting about adverse events to Israeli Ministry of Health can be done via the portal for Reporting Side Effects, found on the home page of Israeli Ministry of Health website www.health.gov.il, or by entering the link <https://sideeffects.health.gov.il/>

This card was revised and approved by Israeli Ministry of Health in March 2020.