

## PATIENT SAFETY INFORMATION CARD

### HADLIMA Adalimumab

This card contains select important safety information that you need to know before and during treatment with Hadlima.

- Keep this card with you at all times and for 70 days after your last injection of Hadlima.
- Show this card to any doctor or health care professional that you see.
- Record information about any tuberculosis (TB) tests or treatment you have had on the back of this card.

#### 1. Introduction

Hadlima is a medicine that is intended to treat certain diseases that affect a part of the immune system. While Hadlima can be effective in treating these diseases, some people can have one or more side effects. It is important to talk to your doctor about the possible benefits and possible side effects of taking Hadlima. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Hadlima.
- Some of the serious side effects that could occur include infections, cancer, and nervous system problems.
- These are not all of the possible side effects of Hadlima.

#### 2. Before Hadlima Treatment

- **Tell your doctor about any health problems you have and any medicines you take.** This will help you and your doctor decide if Hadlima is right for you.
- Tell your doctor if you:
  - have an infection or have symptoms of an infection (such as fever, wounds, feeling tired, dental problems)
  - have tuberculosis or have been in close contact with someone with tuberculosis
  - have or have had cancer
  - have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis.
- Your doctor should check you for signs and symptoms of tuberculosis before starting Hadlima. You may need to be treated for tuberculosis before starting Hadlima. Please record your TB results in the notes section of this card.

#### 3. Vaccinations

- You may receive vaccinations except for live vaccines.
- If you receive Hadlima while you are pregnant, it is important that you inform your baby's doctor before your baby receives any vaccine. Your baby should not receive a 'live vaccine,' such as BCG (used to prevent tuberculosis) within 5 months following your last Hadlima injection during pregnancy.

#### 4. During Hadlima Treatment

- To make sure that Hadlima is working properly and safely for you, you should check in with your doctor regularly to discuss how you are doing. Tell the doctor right away about any changes in your condition.
- Keep your doctor informed about how Hadlima is working for you.

- **It is important to call your doctor right away about any unusual symptoms you may have.** This will help make sure you get the right care. It will also lower the chance of a side effect becoming worse.
  - Many side effects, including infections, can be managed if you tell your doctor right away.
  - If you get a side effect, your doctor will decide if you should continue or stop Hadlima treatment. It is important to talk with your doctor to find out what is right for you.
  - Since side effects can happen after your last dose of Hadlima, tell your doctor about any problems that you may have up to **70 days** after your last injection of Hadlima.
- Tell your doctor about your:
  - new medical conditions.
  - new medicine.
  - surgery or operation planned.

**Some people taking Hadlima may get serious side effects, including:**

***Infections***

Hadlima helps people with certain inflammatory diseases. It does this by blocking a part of the immune system. However, this part of the immune system also helps fight infection. This means Hadlima can make you more likely to get infections or make any infection that you may have worse. This includes infections such as colds or more serious infections like tuberculosis.

***Cancer***

If you take Hadlima, the risk of getting certain types of cancer may increase.

***Nervous system problems***

Some people have developed new or worsening nervous system problems with Hadlima. This includes multiple sclerosis.

Please read the Hadlima package leaflet for more information. These are not all of the possible side effects that may occur during treatment with Hadlima.

By reporting side effects, you can also help provide more information on the safety of this medicine.

**Call your doctor or get medical care right away if you have any of the following symptoms as they may indicate a serious side effect of Hadlima treatment:**

***Infections***

fever, chills, unusual sweating, feeling unwell or more tired than normal, feeling or being sick (such as nausea or vomiting), diarrhea, stomach pain, loss of appetite or weight loss, cough or coughing up blood or mucus, shortness of breath, problems urinating, skin sores, wounds, muscle aches, dental problems

***Cancer***

night sweats; swelling of the lymph nodes (swollen glands) in the neck, armpits, groin or other areas; weight loss; new skin lesions or change in existing skin lesions (such as moles or freckles); severe itchiness that cannot be explained

***Nervous system problems***

Numbness or tingling, vision changes, muscle weakness, unexplained dizziness

Tell your doctor about any unusual symptoms that you may have during treatment with Hadlima. These

are not all of the possible symptoms of these side effects.

### **Information for you and health care professionals involved in your medical care or treatment**

Your Name: \_\_\_\_\_

Doctor's name (who prescribed Hadlima): \_\_\_\_\_

Doctor's phone number: \_\_\_\_\_

Condition prescribed for: \_\_\_\_\_

Date of first Hadlima injection: \_\_\_\_\_

Dose of Hadlima injection: \_\_\_\_\_

Date of last Hadlima injection

(if no longer taking Hadlima): \_\_\_\_\_

### **Tuberculosis (TB) Tests and Treatment**

Mark this box if you have ever **been tested for TB:**

YES (Ask your doctor if you do not know)

Mark this box if you have ever **had any test that was positive for TB:**

YES (Ask your doctor if you do not know)

Mark this box if you have ever **taken any pills to treat or prevent TB:**

YES (Ask your doctor if you do not know)

**Please read the Hadlima package leaflet for more information.** If you have any other questions, talk to your doctor or another health care professional.

### **Adverse events reporting:**

- Reporting about adverse events to Israeli Ministry of Health can be done via the portal for Reporting Side Effects, found in home page of Israeli Ministry of Health website [www.health.gov.il](http://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 Dec 2020.