

## Patient safety information card

Hulio is a bio-similar product. For additional information about bio-similar products refer to the Ministry of Health website:  
<https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx>

### Adalimumab (TNF inhibitor)

Information for you and health care professionals involved in your medical care or treatment. Not all possible side effects are listed on this card. Please read the **Hulio** package leaflet or talk with your doctor for more information about side effects.

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

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

### Introduction

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

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

### Before Hulio Treatment

Tell your doctor about any health problems you have and any medicines you take. This will help you and your doctor decide if **Hulio** 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 to use **Hulio**. You may need to be treated for tuberculosis before you start to take **Hulio**.

### Vaccinations

- You can receive vaccinations, except for live vaccines
- If you are being treated with **Hulio** while you are pregnant, it is important that you inform your pediatrician 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 **Hulio** injection during pregnancy

### During Hulio Treatment

To make sure that **Hulio** is working properly and safely for you, you should check in with your doctor regularly to discuss your condition. Tell your doctor immediately about any change in your condition.

### Keep your doctor informed about how Hulio is affecting you.

- It is important to call your doctor right away about any unusual symptoms you may experience. This will help make sure you get the right treatment. It will also lower the chance of a side effect becoming worse
- Many side effects, including infections, can be treated appropriately if you tell your doctor right away
- If you experience a side effect, your doctor will decide if you should continue or stop the **Hulio** treatment. It is important to talk with your doctor to find out what is right for you
- Since side effects may appear after taking the last dose of **Hulio**, tell your doctor about any problems that you may have up to 70 days after the last injection of **Hulio**

### Tell your doctor about:

- Any new medical conditions that you have
- New medicines you are taking
- Any surgery or procedure that you have planned

### Some people taking Hulio may get serious side effects, including:

#### Infections

- **Hulio** 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 **Hulio** may make you more likely to get infections or make any infection that you have worse. This includes infections such as colds or more serious infections like tuberculosis

#### Cancer

- If you use **Hulio**, the risk of getting certain types of cancer may increase

#### Nervous system problems

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

### Please read the Hulio patient leaflet for more information.

These are not all of the possible side effects that may appear during treatment with **Hulio**.

### Call your doctor or get medical care right away if you have any of the following symptoms of these possible serious side effects:

#### 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 have during treatment with Hulio.

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

#### Tuberculosis (TB) Tests and Treatment

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

- YES** (Check with your doctor if you do not know)

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

- YES** (Check with your doctor if you do not know)

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

- YES** (Check with your doctor if you do not know)

Please read the included **Hulio** patient leaflet for more information.

If you have any other questions, talk to your doctor or another health care professional.

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

Doctor's name  
(who prescribed the medicine Hulio): \_\_\_\_\_

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

Date of your first Hulio injection: \_\_\_\_\_

Dosage of your Hulio injection: \_\_\_\_\_

Date of your last Hulio injection  
(if no longer taking Hulio): \_\_\_\_\_

Please fill out the information for you and health care professionals involved in your medical care or treatment.

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il> Additionally, you can report to the registration holder, Dexcel Ltd., via email at the following address: [CustomerService@dexcel.com](mailto:CustomerService@dexcel.com)