

Hulio adalimumab (adalimumab)

Patient Reminder Card – for use in adults

The Patient Reminder Card is a condition of the Marketing Authorisation.

Information for you and healthcare 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 selected important safety information that you need to know before and during your 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 healthcare professional that you see.
- Record information about any tuberculosis tests or treatment you have had on the inside of this card.

For detailed information about Hulio, read the Package Leaflet which is included in the Hulio package, or talk with your doctor, nurse or pharmacist.

1. 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 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 Hulio. These can 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 could occur include infections, cancer, and nervous system problems.
- These are not all of the possible side effects of Hulio.

2. Before Hulio Treatment

Tell your doctor about any existing 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 Hulio. You may need to be treated for tuberculosis before you start Hulio.

Vaccinations

- You may receive vaccinations except for live vaccines.

- If you receive Huloio 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 Huloio injection during pregnancy.

3. **During Huloio Treatment**

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

Keep your doctor informed about how Huloio is working for you

- It is important to tell your doctor straight 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 your Huloio treatment. It is important to talk with your doctor to find out what is right for you.
- Since side effects can still develop after your last dose of Huloio, tell your doctor about any symptoms that you may have up to 70 days after your last injection of Huloio.

Tell your doctor about:

- any new medical conditions that you have;
- new medicines you are taking;
- any surgery or operation that you have planned.

4. **Some people taking Huloio may get serious side effects, including:**

Infections: Huloio 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 fighting infection. This means Huloio 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 Huloio, the risk of getting certain types of cancer may increase.

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

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

5. **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), diarrhoea, 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 skin lesions (such as moles or freckles) you already have, 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 Hulio. These are not all of the possible symptoms of these side effects.

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.

Alternatively the report can be sent to MAH: medical.informationEU@biocon.com; Tel: 0080008250910.

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

6. Information for you and healthcare 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 Hulio Package Leaflet for more information. If you have any other questions, talk to your doctor or another healthcare professional.

Your name: _____

Doctor's name (who prescribed Hulio): _____

Doctor's phone number: _____

Indication: _____

Date of your first Hulio injection: _____

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Dose of your Hulo injection: _____

Date of your last Hulo injection (if no longer taking Hulo): _____

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