

Hulio adalimumab (adalimumab)

Patient Reminder Card – for use in children

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

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

This card contains selected important safety information that you need to know before and during your child’s treatment with Hulio.

- Keep this card with you at all times and for 70 days after your child’s last injection of Hulio.
- Show this card to any doctor or healthcare professional that your child sees.
- Record information about any tuberculosis tests or treatment your child has 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 child’s 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 child’s doctor about any existing health problems your child has and any medicines your child takes. This will help you and your child’s doctor decide if Hulio is right for your child.

Tell your child’s doctor if your child:

- has an infection or has symptoms of an infection (such as fever, wounds, feeling tired, dental problems);
- has tuberculosis or has been in close contact with someone with tuberculosis;
- has or has had cancer;
- has any numbness or tingling or has a problem that affects his/her nervous system, such as multiple sclerosis;

Your child’s doctor should check your child for signs and symptoms of tuberculosis before starting Hulio. Your child may need to be treated for tuberculosis before he or she starts Hulio.

Vaccinations

Your child’s doctor may suggest certain vaccinations for your child before they start Hulio. Live vaccines should not be administered to your child while taking Hulio. If your child receives Hulio while pregnant, it is important that you inform the baby’s doctor before the baby receives any vaccine. The baby should not receive a “live vaccine,” such as BCG (used to prevent tuberculosis) within 5 months following your child’s last Hulio injection during pregnancy.

3. During Hulio Treatment

To make sure that Hulio is working properly and safely for your child, you should check in with his or her doctor regularly to discuss how your child is doing. Tell your doctor right away about any changes in your child’s condition.

Keep your child’s doctor informed about how Hulio is working for your child.

- It is important to call your child’s doctor right away about any unusual symptoms your child may have. This will help make sure your child gets 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 child’s doctor right away.
- If your child gets a side effect, your child’s doctor will decide if your child should continue or stop his or her Hulio treatment. It is important to talk with your child’s doctor to find out what is right for your child.
- Since side effects can happen after your child’s last dose of Hulio, tell your child’s doctor about any problems that your child may have up to 70 days after your child’s last injection of Hulio.

Tell your child’s doctor about:

- Any new medical conditions that your child has.
- New medicines your child is taking.
- Any surgery or operation that is planned for your child.

4. 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 can make your child more likely to get infections or make any infection that your child may have worse. This includes infections such as colds or more serious infections like tuberculosis.

Cancer: If your child takes 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 package leaflet for more information. These are not all of the possible side effects that may occur during treatment with Hulio.

5. Call your child’s doctor or get medical care right away if your child has 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 has, severe itchiness that cannot be explained.

Nervous system problems

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

Tell your child’s doctor about any unusual symptoms that your child 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 child’s medical care or treatment

Tuberculosis (TB) Tests and Treatment

Mark this box if your child has ever **been tested for TB**:

YES (Check with your child’s doctor if you do not know)

Mark this box if your child has ever **had any test that was positive for TB**:

YES (Check with your child’s doctor if you do not know)

Mark this box if your child has ever **taken any pills to treat or prevent TB**:

YES (Check with your child’s doctor if you do not know)

Please read the Hulio Package Leaflet for more information. If you have any other questions, talk to your child’s doctor or another healthcare professional.

Your child’s name: _____

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Doctor's name (who prescribed Hulo): _____

Doctor's phone number: _____

Indication: _____

Date of your child's first Hulo injection: _____

Dose of your child's Hulo injection: _____

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

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