

Hulio (adalimumab)

Patient Reminder Card – for use in children

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

- Keep this card with you/your child at all times and for 4 months after his/her 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 child’s doctor, nurse or pharmacist.

1. Introduction

Hulio helps people with certain inflammatory diseases. It does this by blocking a part of the immune system which helps fight infection.

While Hulio can be effective in treating these inflammatory diseases, some people can experience one or more side effects. It is important to talk to your child’s doctor about the possible benefits and possible side effects of giving your child Hulio.

Please read the Hulio package leaflet for a full list of possible side effects your child could experience with Hulio treatment.

2. Before Hulio Treatment

Tell your child’s doctor about any existing health problems your child has and any medicines he/she is already taking. 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, or has previously had, tuberculosis or has been in close contact with someone with tuberculosis;
- has, or has previously had, cancer;
- has any numbness or tingling or has a problem that affects his/her nervous system, such as multiple sclerosis;
- has previously had vaccination (type of vaccination, date).

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 you give them Hulio.

Check with your child’s doctor before receiving any vaccines. If possible, bring your child up to date with all the vaccinations scheduled for its age prior to Hulio treatment is initiated.

3. During Hulio Treatment

To make sure that Hulio is working properly and safely for your child, you should meet with your child's doctor regularly to discuss how your child is. Tell your child's doctor straight away about any changes in his/her condition.

It is important to tell your child's doctor straight away about any unusual symptoms or side effects your child may experience. This will help make sure your child gets the right care. It will also lower the chance of a side effect becoming worse.

If your child gets a side effect, your child's doctor will decide if he/she should continue or stop their Hulio treatment.

Since side effects can still develop after your child's last dose of Hulio, tell your child's doctor about any symptoms that he/she may have up to 4 months after his/her last injection of Hulio.

Tell your child's doctor about:

- any new medical conditions that your child develops;
- new medicines your child starts taking,
- any surgery or operation that your child has planned.

4. Side Effects

Please read the Hulio package leaflet for a full list of possible side effects.

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.

Seek urgent medical attention if your child experiences any of the following symptoms as they may indicate a serious side effect of Hulio treatment:

- severe rash, hives or other signs of allergic reaction;
- swollen face, hands or feet;
- trouble breathing or swallowing;
- pale complexion, dizziness, persistent fever, bruising or bleeding very easily.

Some of the other important side effects that your child could develop include:

- **Infections:** 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:** Hulio can increase the risk of getting certain types of cancer.
- **Nervous system problems:** Hulio can cause your child to develop new or worsening nervous system problems. Symptoms your child could develop can include vision change, muscle weakness or unexpected dizziness.
- **Vaccination:** Hulio alters immune response. Administration of live vaccines (e.g. BCG vaccine used against tuberculosis) to your infant exposed to Hulio in-utero is not recommended for 5 months following your last Hulio injection during pregnancy.

Speak to your child's doctor if you suspect your child is suffering from any of the above (see Package Leaflet for symptoms to look out for).

By reporting side effects you can help provide more information on the safety of this medicine. See Package Leaflet for more details.

5. Information for you and healthcare professionals involved in your child's medical care or treatment

Your child's name: _____

Doctor's name (who prescribed Huloio): _____

Doctor's phone number: _____

Indication: _____

Date of your child's first Huloio injection: _____

Dose of your child's Huloio injection: _____

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

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 Huloio Package Leaflet for more information. If you have any other questions, talk to your child's doctor or another healthcare professional.

Notes (comments or questions for your child's doctor):

In case you experience any side effect while on Hulio (adalimumab, report them to:

- Mylan S.A.S
E-mail: PV.MiddleEast@viatris.com
- National Pharmacovigilance and Drug Safety Centre (NPC)
E-mail: npc.drug@sfd.a.gov.sa
Or by online: <https://ade.sfd.a.gov.sa>
Toll free phone: 19999

NOTE: Saudi Food and Drug Authority (SFDA) has reviewed and approved this reminder card.