

Hulio (adalimumab)

Patient Reminder Card – for use in adults

This card contains select 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 4 months 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 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 doctor about the possible benefits and possible side effects of taking Hulio.

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

2. Before Hulio Treatment

Tell your doctor about any existing health problems you have and any medicines you are already taking. 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, or have previously had, tuberculosis or have been in close contact with someone with tuberculosis;
- have, or have previously had, cancer;
- have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis;
- have previously had vaccination (type of vaccination, date).

Your doctor should also check you for signs and symptoms of tuberculosis before starting Hulio. You may need to be treated for tuberculosis before you start Hulio.

3. During Hulio Treatment

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

During Hulio treatment you may receive concurrent vaccinations, except for live vaccines. If you received Hulio while you are pregnant, your baby may be at higher risk for getting an infection and administration of live vaccines is not recommended for up to five months following your last Hulio treatment during pregnancy.

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

If you get a side effect, your doctor will decide if you should continue or stop your Hulio treatment.

Since side effects can still develop after your last dose of Hulio, tell your doctor about any symptoms that you may have up to 4 months after your last injection of Hulio.

Tell your doctor about:

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

4. Side Effects

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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.

Seek urgent medical attention if you experience 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 you could develop include:

- **Infections:** Hulio 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:** Hulio can increase the risk of getting certain types of cancer.
- **Nervous system problems:** Hulio can cause you to develop new or worsening nervous system problems. Symptoms you might develop can include vision changes, 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 doctor if you suspect you are 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 medical care or treatment

Your name: _____

Doctor's name (who prescribed Hulo): _____

Doctor's phone number: _____

Indication: _____

Date of your first Hulo injection: _____

Dose of your Hulo injection: _____

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

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

Notes (comments or questions for your 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.