



Patient Reminder Card – for use in adults

Version (2.0)
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This card contains 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 5 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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. 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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517 Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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 (including tuberculosis), cancer, and nervous system problems;
- These are not all of the possible side effects of Hulio®;
- Certain vaccines may cause infections and should not be given while receiving Hulio®. Please check with your doctor before receiving any vaccines;
- To make sure that Hulio® 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.

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.

Your doctor should check you for signs and symptoms of tuberculosis before starting Hulio®. This will include a medical examination including your medical history and appropriate screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on this card. It is important that you tell your doctor if you have ever had tuberculosis or if you have been in close contact with someone who has had tuberculosis.

Tell your doctor if you:

- 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 an infection including long term or localised infection. It is important to tell your doctor if you have symptoms of an infection (e.g. fever, wounds, feeling tired, dental problems);
- reside or travel in regions where fungal infections such as histoplasmosis, occidoidomycosis or blastomycosis are endemic;
- had previously had vaccination (type of vaccination, date).

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.

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.

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 Hulio® treatment. It is important to talk with your doctor to find out what is right for you.
- Since side effects can happen after your last dose of Hulio®, tell your doctor about any symptoms that you may have up to 5 months after your last injection of Hulio®.

Tell your doctor about:

- Any new medical conditions that you have.
- New medicines you are taking.
- Any surgery or operation that is planned for you

Vaccinations

Certain vaccines contain living but weakened forms of bacteria or viruses that cause diseases and should not be given during treatment with Huloio® in case they cause infections. If you received Huloio® while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose of Huloio® you received during pregnancy. Huloio® alters immune response: administration of live vaccines (e.g. BCG vaccine used against tuberculosis) to your baby is not recommended for up to five months following your last Huloio® injection during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Huloio® use during your pregnancy so they can decide when your baby should receive any vaccine.

4. Side Effects

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 which also helps to fight infection. This means Huloio® can 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 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 the possible side effects that may occur during treatment with Huloio®.

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 changes 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 your treatment with Huloio®. These are not all of the possible side effects that can occur.

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

Your name:

Doctor's name (who prescribed Huloio®):

Doctor's phone number:

Indication:

Date of your first Huloio® injection:

Dose of your Huloio® injection:

Date of your last Huloio® injection (if no longer taking Huloio®):

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 record the date and result of your last screening for TB below:

Tuberculin test:.....

Chest x-ray:.....

Please read the Huloio® 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):

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