



Patient Reminder Card – for use in children

Version (4.0)

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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/your child at all times and for 5 months after his/her last injection of Hulio®.
- Show this card to any doctor or healthcare professional that you see.
- Record information about any tuberculosis tests or treatment your child has 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.

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. Please report side effects with any medicine or vaccine directly via the national reporting system: HPRA Pharmacovigilance, Website: www.hpra.ie. In order to support effective tracking and traceability of biologics including biosimilars, it is recommended that the brand name and batch number are recorded and used when reporting side effects. By reporting side effects you can help provide more information on the safety of this medicine. You should also report any side effects to Biosimilar Collaborations Ireland Limited on 1800777794 or email: medical.informationEU@biocon.com

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 (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 child's doctor before he/she receives any vaccines;
- To make sure that Hulio® is working properly and safely for you, you should check in with his or her doctor regularly to discuss how your child is doing. Tell your child's doctor right away about any changes in your child's condition.

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 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.

Your doctor should check your child for signs and symptoms of tuberculosis before starting Hulio®. This will include a medical examination including your child's 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 your child has ever had tuberculosis or if your child has been in close contact with someone who has had tuberculosis.

Tell your child's doctor if your child:

- has, or has had, cancer;
- has any numbness or tingling or has a problem that affects their nervous system, such as multiple sclerosis;
- has an infection including long term or localised infection. It is important to tell your child's doctor if your child has symptoms of an infection (e.g. fever, wounds, feeling tired, dental problems);
- reside or travels in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic;
- has previously had vaccination (type of vaccination, date).

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

3. During Hulio® Treatment

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 may also help 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 5 months after his or her 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.

Vaccinations

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

4. Side Effects

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 which also helps to fight infection. This means Hulio® can make your child more likely to get infections or make any infection that they 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 the possible side effects that may occur during treatment with Hulio®.

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 changes in skin lesions (such as moles or freckles) your child 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 their treatment with Hulio®. These are not all of the possible side effects that can occur.

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 Hulio®):.....

Doctor's phone number:.....

Indication:.....

Date of your child's first Hulio® injection:.....

Dose of your child's Hulio® injection:.....

Date of your child's last Hulio® injection (if no longer taking Hulio®):.....

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

Tuberculin test:.....

Chest x-ray:.....

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.

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

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