

# Humira® Paediatric Patient Alert Card

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

- Keep this card with you at all times and for 4 months after your last injection of Humira.
- 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.



**If you have any questions, speak  
to your child's doctor or nurse  
about their treatment**

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This material was developed by AbbVie, Inc. as part of the risk minimization plan for Humira.

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This material is not intended for promotional use.

Not all possible side effects are listed on this card.

- Please read the Humira package leaflet or talk with your child's doctor for more information about side effects.

## 1. Introduction

Humira is a medicine that is intended to treat certain diseases that affect a part of the immune system. While Humira 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 Humira.

These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects and their associated symptoms that your child may experience when taking Humira.
- Some of the serious side effects that could occur include infections, heart failure, cancer, and nervous system problems. The symptoms of the side effects that your child may experience are listed further overleaf.
- For a full list of adverse reactions that your child may experience when taking Humira, please read the patient information leaflet which is included in the Humira package.

To make sure that Humira 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 child's doctor right away about any changes in your child's condition.

## 2. Before Humira 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 Humira is right for your child.
- Tell your child's doctor if your child:
  - has any allergies
  - 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 a serious heart condition or heart failure
  - has or has had cancer
  - has any numbness or tingling or has a problem that affects your child's nervous system, such as multiple sclerosis.
- Your child's doctor should check him or her for signs and symptoms of tuberculosis before starting Humira. Your child may need to be treated for tuberculosis before he or she starts Humira.

## 3. During Humira Treatment

- Keep your child's doctor informed about how Humira 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.
  - If your child gets a side effect, your child's doctor will decide if your child should continue or stop his or her Humira treatment.
  - Since side effects can happen after your child's last dose of Humira, tell your child's doctor about any problems that your child may have up to 4 months after his or her last injection of Humira.
- 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.

## Reporting of Side Effects

If you get any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

For any side effects please report to the Medicines Authority at <http://www.medicinesauthority.gov.mt/adrportal> or to the local representative of AbbVie Ltd: V.J. Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel: +356 21 220 174 and 24hPV mobile +356 99644126

By reporting side effects you can help provide more information on the safety of this medicine.

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**Some people taking Humira may get serious side effects, including:**

**Allergic reactions:** Some people may experience an allergic reaction to Humira which can vary in intensity, with symptoms such as, severe rash, hives, swollen hands, feet, face or tongue, difficulty in swallowing, breathing, wheezing or shortness of breath. You should contact your child's doctor immediately if you notice any of these signs. An allergic reaction can vary in intensity and time to onset. Do not wait. Call your child's doctor. Do not inject any more Humira.

**Infections:** Humira 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 Humira 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.

**Heart failure:** some people have developed new heart failure or worsening of heart failure they already had.

**Cancer:** if you take Humira, the risk of getting certain types of cancer may increase.

**Nervous system problems:** some people have developed new or worsening nervous system problems with Humira: multiple sclerosis for example.

**Please read the Humira package leaflet for a full list of possible side effects your child may experience with Humira treatment.**

**Call your doctor or get medical care right away if your child has any of the following symptoms as they may indicate a serious side effect of Humira treatment**

**Allergic reactions:** Severe rash, hives, swollen hands, feet, face or tongue, difficulty in swallowing, breathing, wheezing or shortness of breath. An allergic reaction can vary in intensity and time to onset. **Do not wait. Call your child's doctor. Do not inject any more Humira.**

**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.

**Heart failure:** shortness of breath, swelling of your ankles or feet, sudden weight gain.

**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 have; severe itchiness that cannot be explained.

**Nervous system problems:** numbness or tingling, vision changes, muscle weakness, unexplained

dizziness.

**In addition, tell your child's doctor about any other unusual symptoms not listed in this table that he or she may have during treatment with Humira.**

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**Vaccination Advice**

Patients on Humira may receive concurrent vaccinations, **except for live vaccinations.** Administration of live vaccines to infants who were exposed to adalimumab in the womb is not recommended for 5 months after the mother's last adalimumab injection during pregnancy. Always seek advice from your child's doctor before receiving any vaccinations.

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

Your child's name:  
 Your child's doctor name:  
 (who prescribed Humira):  
 Your child's doctors phone no:  
 Indication:  
 Date of your child's first Humira injection:  
 Dose of your child's Humira injection:  
 Date of your child's last Humira injection  
 (if no longer taking Humira):

Tuberculosis (TB) Tests and Treatment  
 Mark this box if you have ever been tested for TB:  
 EH YES (Check with your child's doctor if you do not know)  
 Mark this box if you have ever had any test that was positive for TB:  
 EH YES (Check with your child's doctor if you do not know)  
 Mark this box if you have ever taken any pills to treat or prevent TB:  
 EH YES (Check with your child's doctor if you do not know)  
 Please read the Humira package leaflet for more information. If you have any other questions, talk to your doctor or another healthcare professional.