

Humira® Patient Alert Card

This card contains important safety information that you need to know before and during 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

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V. have had on the inside of this card.

**If you have any questions, speak
to your doctor or nurse about
your treatment**

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

Contact details for Malta : V.J. Salomone Pharma Ltd.,
Upper Cross Road, Marsa MRS1542, Malta,

Tel: +356 21 220 174 and 24hPV mobile +356 99644126

This material is not intended for promotional use.

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Not all possible side effects are listed on this card.

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

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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 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 you 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 you may experience are listed on the reverse.
- For a full list of adverse reactions you 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 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.

2. Before Humira Treatment

- **Tell your doctor about any health problems you have and any medicines you take.** This will help you and your doctor decide if Humira is right for you.
- Tell your doctor if you:
 - have any allergies
 - have an infection or have symptoms of an infection (such as fever, wounds, feeling tired, dental problems)
 - have tuberculosis or have been in close contact with someone with tuberculosis
 - have or have had a serious heart condition or heart failure
 - have or have had cancer
 - have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis.
- Your doctor should check you for signs and symptoms of tuberculosis before starting Humira. You may need to be treated for tuberculosis before you start Humira.

3. During Humira Treatment

- Keep your doctor informed about how Humira is working for you.
- **It is important to call your doctor right away about any unusual symptoms you may have.** 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 Humira treatment.
 - Since side effects can happen after your last dose of Humira, tell your doctor about any problems that you may have up to 4 months after your last injection of Humira.
- Tell your doctor about:
 - any new medical conditions that you have
 - new medicines you are taking
 - any surgery or operation that you have planned.

Reporting of 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.

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 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 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 you may experience with Humira treatment.

Call your doctor or get medical care right away if you have 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 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 doctor about any other unusual symptoms not listed in this table that you may have during treatment with Humira.

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 doctor before receiving any vaccinations.

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

Your name:

Doctor's name

(who prescribed Humira):

Doctors phone number:

Indication:

Date of your first Humira injection:

Dose of your Humira injection:

Date of your 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 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 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 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.