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Hyrimoz ▼ (Adalimumab) Patient Alert Card

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

- Keep this card with you at all times and for up to 70 days after your or your child's last injection of Adalimumab.
- Show this card to your or your child's doctor or healthcare professional that you or your child sees.
- Record information about any tuberculosis tests or treatment you or your child has had on the inside of this card.

 **SANDOZ**
a Novartis company

UK/NP/HYR/18-0012b Aug 2018

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

Not all possible side effects are listed on this card.

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

1. Introduction

Adalimumab is a medicine that is intended to treat certain diseases that affect a part of the immune system. While Adalimumab can be effective in treating these diseases, some people can have one or more side effects. It is important to talk to your or your child's doctor about the possible benefits and possible side effects of taking Adalimumab. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Adalimumab.
- Some of the serious side effects that could occur include infections [including TB (tuberculosis)], heart failure, cancer, and nervous system problems.

- These are not all of the possible side effects of Adalimumab.

To make sure that Adalimumab is working properly and safely for you or your child, you should check in with your or your child's doctor regularly to discuss how you or your child is doing. Tell your or your child's doctor right away about any changes in your or your child's condition.

2. Before Adalimumab Treatment

- Tell your or your child's doctor about any health problems you or your child has and any medicines you or your child takes. This will help you or your child's doctor decide if adalimumab is right for you or your child.

- Your doctor should check you or your child for signs and symptoms of TB before starting Adalimumab. This will include a medical examination including your or your child's medical history and appropriate screening tests. The conduct and results of these tests should be recorded on this card. It is important that you tell your doctor if you or your child has ever had TB or if you or your child has been in close contact with someone who has had TB.

- **Tell your or your child's doctor if you or your child:**
 - 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 nervous system, such as multiple sclerosis.

- has an infection including long-term or localized infection. It is important that you tell your or your child's doctor if you or your child has symptoms of an infection (e.g. fever, wounds, feeling tired, dental problems).
- resides or travels in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are occurring.

3. During Adalimumab Treatment

- Keep your or your child's doctor informed about how Adalimumab is working for you or your child.
- **It is important to call your or your child's doctor right away about any unusual symptoms you or your child may have.** This will help make sure you or your child gets 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 or your child's doctor right away.
- If you or your child gets a side effect, your or your child's doctor will decide if you or your child should continue or stop Adalimumab treatment.
- Since side effects can happen after you or your child's last dose of Adalimumab, tell your or your child's doctor about any problems that you or your child may have up to 70 days after your or your child's last injection of Adalimumab.

- Tell your or your child's doctor about:
 - any new medical conditions that you or your child has
 - new medicines you or your child is taking
 - any surgery or operation that is planned for you or your child.

Some people taking Adalimumab may get serious side effects, including:

Infections: Adalimumab 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 Adalimumab can make you or your child more likely to get infections or make any infection that you or your child may have worse. This includes infections such as colds or more serious infections like tuberculosis.

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

Cancer: if you or your child takes Adalimumab, the risk of getting certain types of cancer may increase.

Nervous system problems: some people have developed new or worsening nervous system problems with Adalimumab. This includes multiple sclerosis.

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

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 or your child already has; severe itchiness that cannot be explained.

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

Tell your or your child's doctor about any unusual symptoms not listed in this table that you or your child may have during treatment with Adalimumab.

Reporting of Side Effects
If you or your child gets 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 the Yellow Card Scheme (www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google play or Apple App store). By reporting side effects you can help provide more information on the safety of this medicine.

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

Your or your child's name: _____

Your or your child's doctor's name: _____
(who prescribed Adalimumab): _____

Your or your child's doctor's phone no.: _____

Date of your or your child's first Adalimumab injection: _____

Dose of your or your child's Adalimumab injection: _____

Date of your or your child's last Adalimumab injection: _____
(if no longer taking Adalimumab): _____

Tuberculosis (TB) Tests and Treatment
Mark this box if you or your child has ever **been tested for TB:**

YES (Check with your or your child's doctor if you do not know)

Mark this box if you or your child has ever **had any test that was positive for TB:**

YES (Check with your or your child's doctor if you do not know)

Mark this box if you or your child has ever **taken any medicines to treat or prevent TB:**

YES (Check with your or your child's doctor if you do not know)

Please read the Adalimumab package leaflet for more information. If you have any other questions, talk to your or your child's doctor or another healthcare professional

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

This information card is produced by:

Company Name: _____

Address: _____

Telephone number: _____

Date of Preparation: _____

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Artwork Proof Box

Ref: Licence application + update

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| Proof no. 001.2 | Date prepared: 21/08/2018 | Font size: 9pt |
| Colours: ■ Pantone 541 <input type="checkbox"/> ■ Black <input type="checkbox"/> | Fonts: FuturaCEEFF | |
| Dimensions: 85 x 55 mm | | |