

# PAEDIATRIC

Patient reminder card

## **Hyrimoz<sup>®</sup> adalimumab**

Information for you and health care professional involved in your child's medical care or treatment.

Not all possible side effects are listed on this card. Please read the Hyrimoz package leaflet or talk with your child's doctor for more information about side effects

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal> and sent by post or email to;

**P:** Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann. SĠN 3000.

**E:** [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

Healthcare Professionals may also report any adverse events associated with the use of **Hyrimoz** by e-mail at [adverse.event.malta@sandoz.com](mailto:adverse.event.malta@sandoz.com)

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**For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - <http://www.medicinesauthority.gov.mt/rmm> - and download the required material with the latest date.**

## **This Card contains select important safety information that you need to know before and during your child's treatment with Hyrimoz**

- Keep this card with you at all times and for 70 days after your last injection of Hyrimoz
- Show this card to any doctor or health care professional that you see
- Record information about any tuberculosis tests or treatment you have had on the back of this card

### **Introduction**

Hyrimoz is a medicine that is intended to treat certain diseases that affect a part of the immune system. While Hyrimoz 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 Hyrimoz. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Hyrimoz
- Some of the serious side effects that could occur include infections, cancer, and nervous system problems
- These are not all of the possible side effects of Hyrimoz

## **Before Hyrimoz 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 Hyrimoz is right for your child.

### **Tell your child's doctor if your child:**

- 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 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 Hyrimoz. Your child may need to be treated for tuberculosis before he or she starts Hyrimoz.

### **Vaccinations**

- Your child's doctor may suggest certain vaccinations for your child before they start Hyrimoz. Live vaccines should not be administered to your child while taking Hyrimoz. If your child receives Hyrimoz while pregnant, it is important that you inform the baby's doctor before the baby receives any vaccine. It is not recommended to give "live vaccine," such as BCG (used to prevent tuberculosis) to babies exposed to Hyrimoz in the womb until 5 months after the mother's last dose of Hyrimoz during pregnancy

## **During Hyrimoz Treatment**

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

### **Keep your child's doctor informed about how Hyrimoz 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
- 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 Hyrimoz 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 Hyrimoz, tell your child's doctor about any problems that your child may have up to 70 days after your child's last injection of Hyrimoz

### **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

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

### **Infections**

Hyrimoz 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 Hyrimoz 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

### **Cancer**

- If your child takes Hyrimoz, the risk of getting certain types of cancer may increase

### **Nervous system problems**

- Some people have developed new or worsening nervous system problems with Hyrimoz. This includes multiple sclerosis

Please read the Hyrimoz package leaflet for more information. These are not all of the possible side effects that may occur during treatment with Hyrimoz.

**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 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

Tell your child's doctor about any unusual symptoms that your child may have during treatment with Hyrimoz. These are not all of the possible symptoms of these side effects.

# Information for you and healthcare professionals involved in your child's medical care or treatment

## Tuberculosis (TB) Tests and Treatment

**Mark this box if your child has ever been tested for TB:**

**YES** (Check with your 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 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 doctor if you do not know)

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

Your child's name: \_\_\_\_\_

Your child's doctor's name (who prescribed Hyrimoz):  
\_\_\_\_\_

Your child's doctor's phone number: \_\_\_\_\_

Indication: \_\_\_\_\_

Date of your child's first Hyrimoz injection: \_\_\_\_\_

Dose of your child's Hyrimoz injection: \_\_\_\_\_

Date of your child's last Hyrimoz injection  
(if no longer taking Hyrimoz): \_\_\_\_\_

Please fill out information for your child and healthcare professionals involved in your child's medical care or treatment.

This educational material is a part of the conditions of the Marketing Authorisation

For more detailed guidance on **Hyrimoz** please refer to the Summary of Product Characteristics (SmPC) available at: <http://www.ema.europa.eu>

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