

ADULT

Patient reminder card

Hyrimoz[®] adalimumab

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

Not all possible side effects are listed on this card. Please read the Hyrimoz package leaflet or talk with your 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

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

Marketing Authorization Holder: Sandoz GmbH

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Local Distributor: VJ Salomone Pharma Limited – Upper Cross Road, Marsa, MRS 1542, Malta

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 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 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 doctor about any health problems you have and any medicines you take. This will help you and your doctor decide if Hyrimoz is right for you.

Tell your doctor if you:

- 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 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 Hyrimoz. You may need to be treated for tuberculosis before you start Hyrimoz.

Vaccinations

- You may receive vaccinations except for live vaccines.
- If you receive Hyrimoz while you are pregnant, it is important that you inform your baby's doctor before your baby receives any vaccine. Your baby should not receive a 'live vaccine', such as BCG (used to prevent tuberculosis) within 5 months following your last Hyrimoz injection during pregnancy

During Hyrimoz Treatment

To make sure that Hyrimoz 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.

Keep your doctor informed about how Hyrimoz 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
- Many side effects, including infections, can be managed if you tell your doctor right away
- If you get a side effect, your doctor will decide if you should continue or stop your Hyrimoz treatment. It is important to talk with your doctor to find out what is right for you
- Since side effects can happen after your last dose of Hyrimoz, tell your doctor about any problems that you may have up to 70 days after your last injection of Hyrimoz

Tell your doctor about:

- Any new medical conditions that you have
- New medicines you are taking
- Any surgery or operation that you have planned

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 you take 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 doctor or get medical care right away if you have 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 doctor about any unusual symptoms that you 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 medical care or treatment

Tuberculosis (TB) Tests and Treatment

Mark this box if you have ever been tested for TB:

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:

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:

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 doctor or another healthcare professional.

Your name: _____

Doctor's name (who prescribed Hyrimoz): _____

Doctor's phone number: _____

Indication: _____

Date of your first Hyrimoz injection: _____

Dose of your Hyrimoz injection: _____

Date of your last Hyrimoz injection (if no longer taking Hyrimoz): _____

Please fill out information for you and healthcare professionals involved in your 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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