

ADULT Patient Reminder Card

This card contains important safety information that you need to know before and during your treatment with Hyrimoz.

- Keep this card with you at all times and for up to 4 months after your last injection of Hyrimoz.
- 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 doctor or nurse about your 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.

1. 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.
- Certain vaccines should not be given during treatment with Hyrimoz in case they cause infections.

2. Before Hyrimoz Treatment

- Tell your doctor about any health problems you have and any medicines you take. This will help the 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 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 starting Hyrimoz.

3. Vaccinations

- You may receive certain vaccinations while taking Hyrimoz however live vaccines should not be administered to you while taking Hyrimoz.
- If you receive Hyrimoz while pregnant, it is important that you inform your baby's doctor before the baby receives any vaccine.

Your baby should not receive a 'live vaccine', such as BCG (used to prevent tuberculosis) until 5 months after your last dose of Hyrimoz during pregnancy.

4. 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 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 4 months 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 is planned for you

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 lymphoma, leukaemia or other cancers may increase. Cases of non-melanoma skin cancer have been observed in patients taking adalimumab.

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.

Your name: _____

Your doctor's name:
(who prescribed Hyrimoz): _____

Your doctor's phone no.: _____

Date of your first
Hyrimoz injection: _____

Dose of your
Hyrimoz injection: _____

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

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 medicines to treat or prevent TB:**

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

Please record the **date and results of your last screening for TB** below.

Tuberculin Test Date: _____

Tuberculin Result: _____

Chest X-ray Date: _____

Chest X-ray Result: _____

Please read the Hyrimoz package leaflet for more information.

If you have any other questions, talk to your doctor or another healthcare professional

▼ This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie Side effects could also be reported to Novartis preferably via www.report.novartis.com, or by email to drugsafety.dublin@novartis.com or by calling 01 2080 612.