

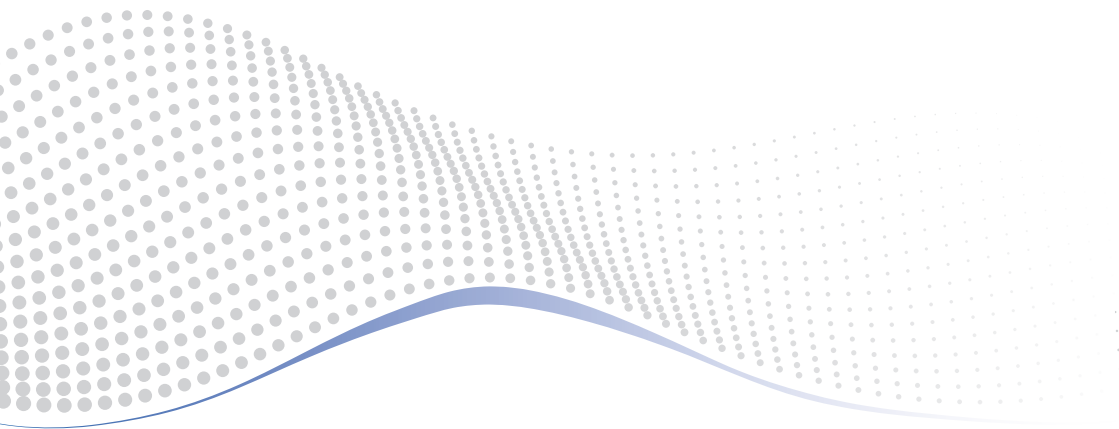
PAEDIATRIC

Patient reminder card

Hyrimoz[®]

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.

SANDOZ A Novartis
Division

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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 child's last injection of Hyrimoz

Show this card to any doctor or health care professional that your child sees

Record information about any tuberculosis tests or treatment your child has 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

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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

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

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You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia -

Toll Free Number: 8001240078

Phone: +966112658100

Fax: +966112658107

Email: adverse.events@novartis.com

Website: <http://report.novartis.com/>

Saudi Food and Drug Authority National Pharmacovigilance Center

Unified Contact Center: 19999

Toll Free Number: 80024900000

Fax: +966112057662

Email: npc.drug@sfd.gov.sa

Website: <https://ade.sfda.gov.sa>

This document has been approved by Saudi Food and Drug Authority (SFDA).

يمكنك الإبلاغ عن أي أعراض جانبية أو شكاوى أو لطلب نسخ إضافية من خلال:

شركة نوفارتيس - السعودية - قسم سلامة المرضى:

الرقم المجاني: ٨٠٠١٢٤٠٠٧٨

الهاتف: ٩٦٦١١٢٦٥٨١٠٠

الفاكس: ٩٦٦١١٢٦٥٨١٠٧

البريد الإلكتروني: adverse.events@novartis.com

الموقع الإلكتروني: <http://report.novartis.com/>

المركز الوطني للتحفظ و السلامة الدوائية - الهيئة العامة للغذاء والدواء:

مركز الاتصال الموحد: ١٩٩٩٩

الرقم المجاني: ٨٠٠٢٤٩٠٠٠٠

الفاكس: ٩٦٦١١٢٠٥٧٦٦٢

البريد الإلكتروني: npc.drug@sfd.gov.sa

الموقع الإلكتروني: <https://ade.sfda.gov.sa/>

هذا الملف تم إعداده من قبل الهيئة العامة للغذاء والدواء في السعودية.