

Idacio® Patient Information Card

This card contains select important safety information that you need to know before and during treatment with Idacio

- Keep this card with you at all times and for 70 days after your last injection of Idacio®
- 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 back of this card.

Introduction

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

- The purpose of this card is to tell you about some of the side effects of Idacio
- 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 Idacio®.

Before Idacio® treatment

Tell your doctor about any health problems you have and any medicines you take. This will help you and your doctor decide if Idacio® 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 Idacio®. You may need to be treated for tuberculosis before you start Idacio®.

Vaccinations

- You may receive vaccinations except for live vaccines.
- If you receive Idacio® 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 Idacio® injection during pregnancy

During treatment with Idacio

To make sure that Idacio® 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 Idacio® is working for you.

- It is important that you call your doctor right away about any unusual symptoms you may have. This would 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 Idacio® 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 Idacio®, tell your doctor about any problems that you may have up to 70 days after your last injection of Idacio®

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 Idacio® may get serious side effects, including:

Infections

- Idacio® 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 Idacio® can make you more likely to get infections or make any infection that you may have worsen. This includes infections such as colds or more serious infections like tuberculosis.

Cancer

- If you take Idacio®, the risk of getting certain types of cancer may increase

Nervous system problems

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

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

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) diarrhea, 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 other unusual symptoms that you may have during treatment with Idacio®. 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 Idacio 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 Idacio®): _____

Doctor's phone number: _____

Indication: _____

Date of your first Idacio® injection: _____

Dose of your Idacio® injection: _____

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

Please fill out information for you and healthcare professionals involved in your medical care or treatment

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to a portal, or by the following link:
<https://sideeffects.health.gov.il>

And by emailing the Registration Holder's Patient Safety Unit at:
drugsafety@neopharmgroup.com
Tel: 1-800-250-255

