IDACIO®▼ (adalimumab) Patient Alert Card

This card outlines the important safety information that you need to be aware of prior to and throughout treatment with IDACIO®.

Cover Position

Patient Alert Card

- Keep this card with you at all times whilst you are taking Idacio® and 4 months after your last injection
- Present this card to all healthcare professionals that you visit
- Not all possible adverse events are listed in this card.
 For a full list, please read the Package Leaflet or ask your doctor for more information about the side effects
- Speak to your doctor or nurse if you have any questions about the possible benefits and side effects of your treatment, and any other information concerning Idacio®
- Please make a note of any tuberculosis tests or treatments you have had inside this card

Introduction

Idacio® is a therapy that aims to treat conditions that are related to the immune system, such as arthritis and psoriasis. Because your medicine targets parts of the immune system that lead to these conditions, some patients can experience one or more side effects.

This card will tell you about some of the side effects and associated symptoms that could affect you while taking Idacio[®].

Some of the serious side effects that you could experience include infections, heart failure, cancer and nervous system problems.

Certain vaccines may cause infection and should not be given while receiving Idacio®, especially live vaccines. Please check with your doctor before you receive any vaccines.

For a complete list of these adverse reactions, please read the Package Leaflet.

Before treatment with Idacio®

Tell your doctor about any health problems that you may have and any medications that you may be taking. This includes whether you have:

- Have an infection including long-term or localised infection. It is important that you tell your doctor if you have symptoms of an infection (e.g. fever, wounds, feeling tired, dental problems).
- Reside or travel in regions where fungal infections such as histoplasmosis, coccidomycosis or blastomycosis are endemic.
- Currently or previously had a serious heart condition, heart failure or cancer
- Numbness, tingling or a problem affecting your nervous system, such as multiple sclerosis

Your doctor should check you for signs and symptoms of tuberculosis before starting Idacio[®]. This will include a medical examination including your medical history and appropriate screening tests (e.g. chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on this card. It is important that you tell your doctor if you have ever had tuberculosis or if you have been in close contact with someone who has had tuberculosis.

If you receive Idacio® while you are pregnant, your baby maybe at higher risk for getting an infection for up to approximately five months after the last Idacio® dose you receive during pregnancy. Also, if the patient receives Idacio® while pregnant, the baby should not receive a 'live vaccine', such as BCG within 5 months following their last Idacio® injection during pregnancy. It is important that you tell your baby's doctor and other healthcare professionals about your Idacio® use during your pregnancy so they can decide when your baby should receive any vaccine.

During treatment

Keep your doctor notified about how your medicine is working for you.

It is important that you call your doctor as soon as you notice any unusual symptoms. This is to ensure that you get the right care immediately, lowering the risk of any side effects worsening.

If your doctor confirms that you have a side effect, he or she will decide whether or not to continue your treatment with Idacio®.

Since side effects can happen after your last dose of Idacio® tell your doctor about any problems you may have up to 4 months after your last injection of Idacio®.

We can get more valuable information on the safety of this medicine when you report any of the side effects you may experience as soon as you notice them.

Tell your doctor about any new conditions and medications that you may have, or any surgery or operations that you may have planned.

Side effects

If you get any of the following symptoms, call your doctor to get immediate medical care, as it may mean you are experiencing a serious side effect of Idacio[®].

Infections

Idacio® helps people with certain inflammatory disease. 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 worse. This risk may increase if you have problems with your lungs.

These infections may be serious and include tuberculosis infections caused by viruses, fungi, parasites or bacteria and severe infections in the blood (sepsis). In rare cases these infections may be life threatening.

Associated symptoms:

Fever; chills; unusual sweating; feeling unwell; fatigue; nausea or vomiting; diarrhoea; stomach pain; loss of appetite; weight loss; cough or coughing up blood or mucus; shortness of breath; urinary problems; skin sores; wounds; muscle aches; dental problems.

Back cover Position

Side effects (cont.)

Heart failure

Idacio® may increase the likelihood of heart failure or of existing heart failure worsening.

Associated symptoms:

Shortness of breath; swelling of ankles or feet; sudden weight gain.

Cancer

If you take Idacio® the risk of getting lymphoma (a cancer that affects the lymph system), leukaemia (a cancer that affects the blood and bone marrow) or other cancers may increase. On rare occasions, an uncommon and severe type of lymphoma has been seen in patients taking adalimumab. Some of these patients were also treated with azathioprine or 6 mercaptopurine.

There have been cases of cancers other than lymphoma in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNF blocker. If you have COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

Cases of non-melanoma skin cancer have also been observed in patients taking adalimumab.

Associated symptoms:

Night sweats; swollen glands in the neck, armpits, groin or other areas; weight loss; new or changed appearance of skin lesions (such as moles or freckles); unusual severe itchiness.

Nervous system problems

Idacio® may make it more likely for you to develop nervous system problems or to have existing nervous system problems worsen, such as multiple sclerosis.

Associated symptoms:

Numbness or tingling; vision changes; muscle weakness; unusual dizziness.

For a full list of side effects that could occur while taking Idacio®, please read the Package Leaflet or ask your doctor for more information about side effects.

In addition to this list, tell your doctor about any other unusual symptoms not listed here that affect you while taking Idacio[®].

Information for you and your healthcare professionals

Your name:
Physician's name who prescribed Idacio®:
Doctors phone number:
Condition treated:
Date of your first injection:
Dose of your injection:
Date of your last injection:

Tuberculosis (TB) tests and treatment

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

Tuberculin test date:	

Tuberculin test result:

Chest X-ray date:

Chest X-ray result:

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 Package Leaflet for more information. If you have any other questions, talk to your doctor.

Notes (somewhat or suppliers for your doctor)

This medicine is subject to additional monitoring.
This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.

You can also report side effects directly via:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance Website: www.hpra.ie

Side effects should also be reported to Fresenius Kabi at Email: pharmacovigilance.GB@fresenius-kabi.com

By reporting side effects you can help provide more information on the safety of this medicine. Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT.

Contact Medical Information Tel: +44 1928 533 575 www.medinfo.fresenius-kabi.co.uk



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