

IDACIO[®] ▼ (adalimumab) Paediatric Patient Alert Card

This card outlines the important safety information that you need to be aware of prior to and throughout your child's treatment with IDACIO[®].

Paediatric Patient Alert Card

Cover position

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

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

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

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

Before treatment with Idacio®

Tell your child's doctor about any health problems that your child may have and any medications that your child may be taking.

Your doctor should check your child for signs and symptoms of tuberculosis before starting Idacio®. This will include a medical examination including your child's medical history and appropriate screening tests (for example 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 your child has ever had tuberculosis or if your child has been in close contact with someone who has had tuberculosis.

Tell your doctor if your child:

- Has an infection including long-term or localised infection. It is important that you tell your doctor if your child has symptoms of an infection (e.g. fever, wounds, feeling tired, dental problems).
- Resides or travel in regions where fungal infections such as histoplasmosis, coccidiomycosis 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
- Certain vaccines may cause infections and should not be given while receiving Idacio®. Please check with your doctor before your child receives any vaccines.
- If your child receives Idacio® while pregnant, the baby maybe at higher risk for getting an infection for up to approximately five months after the last Idacio® dose received 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 the baby's doctor and other healthcare professionals about your child's Idacio® use during pregnancy so they can decide when the baby should receive any vaccine.

During treatment

Keep your child's doctor notified about how this medicine is working for your child.

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

If your child's doctor confirms that your child has a side effect, he or she will decide whether or not to continue your child's treatment with Idacio®.

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

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

Side effects

If your child gets any of the following symptoms, call your child's doctor for them to get immediate medical care, as it may mean your child is 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 your child more likely to get infections or make any infection that your child may have worse.

This risk may increase if your child has problems with their 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.

Back cover position

Side effects (cont.)

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.

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 your child takes 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.

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 your child 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 child's doctor for more information about side effects.

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

Information for you and your child's healthcare professionals

Your child's name: _____

The name of your child's physician, who prescribed Idacio®: _____

Doctors phone number: _____

Condition treated: _____

Date of first injection: _____

Dose of injection: _____

Date of last injection: _____

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)

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

Notes (comments or questions for your child's 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.

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Contact Medical Information
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**FRESENIUS
KABI**

caring for life

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