

PAEDIATRIC Patient Reminder Card

HUMIRA[®] adalimumab (TNF Inhibitor)

Information for you and health care professionals involved in your child's medical care or treatment. **Not all possible side effects are listed on this card.** Please read the Humira package leaflet or talk with your child's doctor for more information about side effects.



Dose of your child's Humira injection: _____
Date of your child's last Humira injection (if no longer taking Humira): _____

Tuberculosis (TB) Tests
Please record the date and results of your child's last screening for TB below:
Tuberculin test: _____
Chest X-ray: _____

Please read the Humira package leaflet for more information.
If you have any other questions, talk to your child's doctor or another health care professional.
Please fill out information for your child and health care professionals involved in your child's medical care or treatment.

Information for you and health care professionals involved in your child's medical care or treatment

Your child's name: _____

Your child's doctor's name (who prescribed Humira): _____

Your child's doctor's phone number: _____

Pharmacy name: _____

Pharmacy phone number: _____

Date of your child's first Humira injection: _____

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) your child already has; 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 Humira. These are not all of the possible symptoms of these side effects.

 **Call your child's doctor or get medical care right away if your child has 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

Disease (COPD) treated with another TNF blocker. If your child has COPD, or is a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for your child.

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

Nervous system problems:
• Some people have developed new or worsening nervous system problems with Humira. This includes multiple sclerosis.

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

severe infection in the blood (sepsis). In rare cases, these infections can be life-threatening.

Cancer:
• If your child takes Humira, 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 Humira. Some of those 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

Some people taking Humira may get serious side effects, including:

Infections:
• Humira 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 Humira 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 his/her lungs. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria,

This card contains select important safety information that you need to know before and during your child's treatment with Humira.

- Keep this card with you at all times and for 5 months after your child's last injection of Humira.
- 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.

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Introduction

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

- The purpose of this card is to tell you about some of the possible side effects of Humira.
- Some of the serious side effects that could occur include infections (including tuberculosis), cancer, and nervous system problems.

- Certain vaccines may cause infections and should not be given while receiving Humira. Please check with your doctor before your child receives any vaccines
- These are not all of the possible side effects of Humira.

2

Before Humira 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 Humira is right for your child.

- Your doctor should check your child for signs and symptoms of tuberculosis before starting Humira. 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 child's doctor if your child:

- Has or has had cancer.
- Has any numbness or tingling or has a problem that affects their nervous system, such as multiple sclerosis.
- 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 travels in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic.

3

Vaccinations

- Certain vaccines may cause infections and should not be given while receiving Humira. Please check with your doctor before your child receives any vaccines. If your child receives Humira while pregnant, the baby may be at higher risk for getting such an infection for up to approximately five months after the last Humira dose your child received during pregnancy. It is important that you tell the baby's doctors and other health care professionals about your child's Humira use during her pregnancy so they can decide when her baby should receive any vaccine.

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During Humira Treatment

To make sure that Humira is working properly and safely for your child, you should check in with his or her doctor regularly to discuss how they are doing. Tell your doctor right away about any changes in your child's condition. Keep your child's doctor informed about how Humira 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 may also help 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 Humira 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 Humira, tell your child's doctor about any problems that your child may have up to 4 months after your child's last injection of Humira. 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.