

Call your child's doctor or get medical care right away if your child has any of the following symptoms that might indicate serious side effects.

Infection:

- Fever
- Chills
- Unusual sweating
- Feeling unwell or feeling more tired than normal
- Throwing up (vomiting) or feeling like he or she is going to throw up (nausea)
- Diarrhoea
- Stomach pain
- Not feeling hungry the way he or she usually does (loss of appetite)
- Losing weight
- Coughing or coughing up blood or mucus
- Feeling like he or she can't catch his or her breath (shortness of breath)
- Problems peeing (urinating)
- Non-healing sores and wounds on his or her skin
- Sore muscles
- Problems with his or her teeth or gums

Cancer:

- Night sweats
- Swollen glands in his or her neck, armpits, groin, or other areas
- Weight loss
- New skin lesions or a change in skin lesions (such as moles or freckles) he or she already had
- Severe itchiness that cannot be explained

Nervous system problems:

- Feeling numbness or tingling anywhere in his or her body
- Changes in vision
- Muscle weakness
- Dizziness

Tell your child's doctor about any unusual symptoms that they have during treatment. These are not all of the possible symptoms of these side effects.

Information for your child and healthcare professionals involved in your child's care

Your child's name: _____

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

Your child's doctor's telephone number: _____

Date of your child's first HUKYNDRA injection: _____

Date of your child's last HUKYNDRA injection if their treatment has finished: _____

Dose of HUKYNDRA: _____

Tuberculosis tests and treatment

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

Tuberculin test: _____

Chest X-ray: _____

Has your child ever tested positive for tuberculosis?

Yes No

Did your child receive treatment for having a positive tuberculosis test?

Yes No

How long was your child treated for tuberculosis? _____

Information about any tuberculosis tests or treatment my child has had:

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If your child gets any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

Hukyndra[®]
adalimumab

Patient Reminder Card for your child

This card has important safety information about HUKYNDRA

Please be sure to:

- Show this card to all of your child's doctors and other healthcare providers. This is so they know your child is taking HUKYNDRA
- Keep this card with you at all times while your child is taking HUKYNDRA and for 5 months after your child's last injection of HUKYNDRA.
- In the notes section on the back of this card, write down information about any tuberculosis tests or treatment your child has had.

The possible side effects listed on this card are not the only possible side effects of HUKYNDRA. For more comprehensive information, please read the HUKYNDRA package leaflet included in the HUKYNDRA package or available on www.hpra.ie or talk with your child's doctor.

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What is HUKYNDRA?

The immune system normally protects the body from infection, but in some disease states (autoimmune diseases) this system doesn't work the way it should. HUKYNDRA is a medicine that is used to treat certain autoimmune diseases. The purpose of this card is to inform you about some of the side effects associated with HUKYNDRA.

Side effects that could happen with HUKYNDRA include:

- Infections (including tuberculosis)
- Cancer
- Problems with your child's nervous system

These are not all of the possible side effects of HUKYNDRA.

Certain vaccines may cause infections and should not be given while receiving HUKYNDRA. Please check with your child's doctor before your child receives any vaccines.

What should I know before my child starts treatment with HUKYNDRA?

The benefits and risks of taking HUKYNDRA vary from person to person. Before your child starts treatment with HUKYNDRA, you should talk with his or her doctor about the benefits and risks for your child. Before your child starts treatment, you should tell his or her doctor:

- About any health problems your child has
- About any medicines your child takes (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
- If your child:
 - Has an infection or symptoms of an infection (such as fever, non-healing sores, wounds, feeling tired, dental problems)
 - Has tuberculosis currently or has had it in the past or has been in close contact with someone who has tuberculosis

- Has cancer or has had it in the past
- Ever feels any numbness or tingling
- Has a problem that affects his or her nervous system, such as multiple sclerosis
- Reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic

Your doctor will check your child for signs and symptoms of tuberculosis before starting treatment with HUKYNDRA. This will include a medical evaluation including 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. Your child may need to be treated for tuberculosis before he/she starts treatment with HUKYNDRA.

Vaccination advice

Certain vaccines may cause infections and should not be given while receiving HUKYNDRA. Please check with your child's doctor before your child receives any vaccines. It is recommended that children, if possible, be given all scheduled vaccines for their age prior to initiating HUKYNDRA.

If your daughter received HUKYNDRA while pregnant, her baby may be at higher risk for getting such an infection for up to approximately five months after the last dose she received during pregnancy. It is important that you tell the baby's doctors and other health care professionals about your daughter's HUKYNDRA use during her pregnancy so they can decide when the baby should receive any vaccine.

What should I do during my child's treatment with HUKYNDRA?

During your child's treatment, you should:

- Keep your child's doctor informed about how HUKYNDRA is working for your child.
- Call your child's doctor right away about any side effects or unusual symptoms they have. Your child's doctor may be able to help you manage the side effects and stop them from getting worse.

- If your child does have a side effect, his or her doctor will decide if your child should keep taking HUKYNDRA.

- Tell your child's doctor about any side effects your child has up to 4 months after the last injection of HUKYNDRA. This is because side effects can happen after the last dose of HUKYNDRA.
- Tell your child's doctor about:
 - Any new medical conditions that your child has
 - New medicines your child is taking (including prescription medicines and over-the-counter medicines, vitamins, and supplements)
 - Any surgery or operation that your child is having

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

Infections — People treated with HUKYNDRA are more likely to get infections and, when they do, the infections are more severe. Some of these infections are relatively minor, such as a common cold. Others are more serious and potentially fatal, such as tuberculosis.

Cancer — If your child takes HUKYNDRA, 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 HUKYNDRA. 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 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 HUKYNDRA.

Nervous system problems — Some people treated with HUKYNDRA can develop new or worsening nervous system problems. This includes multiple sclerosis.