

## **Yuflyma<sup>®</sup> (adalimumab) Paediatric Patient Reminder Card**

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

- Keep this card with you at all times and for up to 4 months after your child's last injection of Yuflyma.
- Present this card to any doctor or healthcare professional that your child sees.
- Record information about any tuberculosis tests or treatment your child has had inside of this card.

**If you have any questions, speak to your child's doctor or nurse about your child's treatment.**

Not all possible side effects are listed on this card. Please read the Yuflyma package leaflet or talk with your child's doctor for more information about side effects.

## Introduction

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

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

## Before Yuflyma Treatment

Tell your child's doctor about any health problems your child has and any medicines your child takes. This will help the doctor decide if Yuflyma is right for your child.

Tell your child's doctor if your child:

- Has an infection or symptoms of an infection (such as fever, wounds, feeling tired, dental problems)
- Has tuberculosis or has been in close contact with someone with tuberculosis.
- Has or has had cancer
- Has any numbness or tingling or has a problem that affects your child's nervous system such as multiple sclerosis

Your child's doctor should check your child for signs and symptoms of tuberculosis before starting Yuflyma. Your child may need to be treated for tuberculosis before he or she starts Yuflyma.

## Vaccination

Your child's doctor may suggest certain vaccinations for your child before they start Yuflyma. Live vaccines should not be administered to your child while taking Yuflyma. If your child receives Yuflyma while pregnant, it is important that you inform the baby's doctor before the baby receives any vaccine. The baby should not receive a "live vaccine", such as BCG (used to prevent tuberculosis) within 5 months following the mother's last Yuflyma injection during pregnancy.

## During Yuflyma Treatment

To make sure that Yuflyma is working properly and safely for your child, you should check in with your child's doctor regularly to discuss how your child is doing. Tell the doctor right away about any changes in your child's condition.

**Keep your child's doctor informed about how Yuflyma 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 will also 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 Yuflyma 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 Yuflyma, tell your child's doctor about any problems that your child may have up to 4 months after your child's last injection of Yuflyma.

**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.

**Some people taking Yuflyma may get serious side effects, including:**

**Infections:** Yuflyma 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 Yuflyma can make your child more likely to get infections or make any infection that your child may have worse. This includes infections such as colds or more serious infections like tuberculosis.

**Cancer:** If your child takes Yuflyma, the risk of getting certain types of cancer may increase.

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

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

**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 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, muscles weakness, unexpected dizziness.

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

**Please read the Yuflyma package leaflet for more information.** If you have any other questions, talk to your doctor or another healthcare professional

**Please fill out information for your child and healthcare professionals involved in your child's medical care or treatment.**

**Tuberculosis (TB) Tests and Treatment** (Check with your child's doctor if you do not know)

Mark this box if your child has ever **been tested for TB**:

Yes     No

Mark this box if your child has ever **had any test that was positive for TB**:

Yes     No

Mark this box if your child has ever **taken any medicines to treat or prevent TB**:

Yes     No

Your child's name: \_\_\_\_\_

Your child's doctor's name  
(who prescribed Yuflyma): \_\_\_\_\_

Your child's doctor's phone no.: \_\_\_\_\_

Condition treated: \_\_\_\_\_

Date of your child's first Yuflyma injection: \_\_\_\_\_

Dose of your child's Yuflyma injection: \_\_\_\_\_

Date of your child's last Yuflyma injection  
(if no longer taking Yuflyma): \_\_\_\_\_

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:

Mint Health Ltd, 3/4 Cantrija Complex, Triq it-Targa, 11-Maghtab, Naxxar NXR6613 Malta

Tel: +356 2093 9800

Email: [pharmacovigilancemt@mint.com.mt](mailto:pharmacovigilancemt@mint.com.mt)

Or report to:

ADR Reporting, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

Email: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

Website: [www.medicinesauthority.gov.mt/adversedrugreactions?l=1](http://www.medicinesauthority.gov.mt/adversedrugreactions?l=1)

Patient reminder card may be downloaded from: <https://medicinesauthority.gov.mt/rmm>

This information card is produced by:

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