

Introduction

Yuflyma is a medicine intended for the treatment of diseases that influence a certain part of the immune system. Yuflyma can be effective in the treatment of these diseases, but it can also cause side effects in some people. It is important to discuss the potential benefits and side effects of Yuflyma with your child's doctor. These can be individual to each patient.

- This Patient Reminder Card describes some of the potential side effects associated with Yuflyma.
- Potential serious side effects include infections, cancer and nervous system dysfunctions.
- This is not an exhaustive list of the potential side effects of Yuflyma.

Before Yuflyma treatment

Tell the doctor about your child's health problems and the medicines they take. This will help the doctor decide whether your child should receive Yuflyma.

Tell your child's doctor if:

- your child has an infection or symptoms of an infection (such as fever, ulcers, fatigue or dental problems)
- your child has tuberculosis or they have been in close contact with someone who has tuberculosis
- your child has or has had cancer
- your child has numbness or tingling in any part of their body or a neurotropic disease, such as multiple sclerosis (MS).

Your child's doctor will determine whether your child has signs or symptoms of tuberculosis before they start receiving Yuflyma. If your child has tuberculosis, they must recover from it before the Yuflyma treatment can begin.

Vaccination

The doctor can recommend certain vaccinations before your child starts receiving Yuflyma. Attenuated live vaccines must not be given during Yuflyma treatment. If your child has received Yuflyma during pregnancy, mention this to your child's doctor before your child is vaccinated. The child must not be given attenuated live vaccines, such as the BCG vaccine (immunisation against tuberculosis), for up to approximately five months after the last Yuflyma dose the mother received during pregnancy.

During Yuflyma treatment

To ensure the effectiveness and safety of your child's Yuflyma treatment, you must have regular appointments with the doctor to discuss your child's health. Tell your child's doctor immediately if you notice changes in the child's general condition.

Tell your child's doctor how Yuflyma has influenced the child's health.

- **It is important to call your child's doctor immediately if the child experiences abnormal symptoms.** This will help ensure that your child receives the right care and reduce the risk of worsening side effects. Many side effects, such as infections, can be treated if you tell your child's doctor about them immediately.

- If your child experiences side effects, their doctor will decide if the child should continue to receive Yuflyma. It is important to consult your child's doctor about what is the best option for the child.
- Because side effects may occur even after your child's last Yuflyma dose, you should tell your child's doctor about any symptoms that may appear within four months after the last Yuflyma injection.

Tell your child's doctor about:

- your child's new diseases
- your child's new medications
- operations and procedures planned for your child.

Some Yuflyma patients may experience serious side effects, such as:

Infections: Yuflyma is intended for the treatment of certain inflammatory diseases. It works by suppressing a certain part of the immune system. However, this part of the immune system helps the body fight off infections. Your child might get infections more easily or their current infections may worsen while the child is receiving Yuflyma treatment. These infections include the common cold and more serious infections, such as tuberculosis.

Cancer: The risk of certain cancers can increase during Yuflyma treatment.

Nervous system: Some people have developed new or worsening nervous system dysfunctions during adalimumab treatment. These include multiple sclerosis.

You can find comprehensive information in the Yuflyma patient information leaflet. This Patient Reminder Card does not mention all the potential side effects of Yuflyma treatment.

Call your child's doctor or seek treatment immediately if your child experiences any of the symptoms of:

Infections: fever, cold shivers, abnormal sweating, nausea or abnormal fatigue, sickness or vomiting, diarrhoea, stomach pain, loss of appetite or weight loss, cough or bloody sputum or productive cough, shortness of breath, difficulty urinating, skin wounds or ulcers, muscle pain, dental problems.

Cancer: night sweats, enlargement of cervical, axillary, inguinal or other lymph nodes, weight loss, new or changed skin changes (such as pigmented moles or freckles), severe unexplained itch.

Nervous system: tingling or numbness, changes in vision, muscle weakness, sudden dizziness.

Tell your child's doctor about any abnormal symptoms that occur during Yuflyma treatment. This Patient Reminder Card does not contain all the potential symptoms of side effects.

You can find comprehensive information in the Yuflyma patient information leaflet.

If you have any questions, please consult your doctor or another healthcare professional.

Fill in the following information for your child and the healthcare professionals involved in your child's treatment.

Tuberculosis tests and treatment

(Consult your child's doctor if you are unsure) Tick the box if **your child has ever been tested for tuberculosis**:

Yes

Tick the box if **your child has ever tested positive for tuberculosis**:

Yes No

Tick the box if **your child has ever been treated or received medication for tuberculosis or its prevention**:

Yes No

If you notice any side effects, consult your child's doctor, pharmacy personnel or a nurse. You can also report the side effects directly:

website: www.fimea.fi

Finnish Medicines Agency
Fimea Adverse Reaction register
PO Box 55
00034 FIMEA

This also applies to side effects that have not been specified in the patient information leaflet. By reporting the side effects,

you contribute to enhancing awareness of the safety of this pharmaceutical product.

Child's name:

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Child's doctor's name (prescriber of Yuflyma):

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Child's doctor's telephone number:

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Disease treated:

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Date of the first Yuflyma injection:

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Yuflyma dose:

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Date of the last Yuflyma injection (if the child is no longer receiving Yuflyma):

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Always write down the product name and lot of the medicine packet:

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RMP v1.1

Approved by Fimea on 18 August 2023.

▼ **This medicinal product is subject to additional monitoring.**



Celltrion Healthcare Finland Oy.

Yuflyma (adalimumab)

Child Patient Reminder Card

This Patient Reminder Card contains important safety information which you must be aware of before starting and during your child's Yuflyma treatment.

- Keep this Patient Reminder Card with you during the treatment period and for four months after your child's last Yuflyma injection.
- Show this Patient Reminder Card to all the doctors or healthcare professionals involved in your child's treatment.
- Write down any tuberculosis tests taken and your child's antituberculosis drugs on the inside page of the card.

If you have any questions, consult a doctor or nurse about your child's treatment.

This Patient Reminder Card does not list all the potential side effects. Read the Yuflyma package leaflet or consult your child's doctor for more information about the side effects of Yuflyma.