

Yuflyma

Adalimumab (TNF inhibitor)

Patient information card

Information for you and health care professionals involved in your medical care or treatment.

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

This card contains selected important safety information that you need to know before and during treatment with Yuflyma

- Keep this card with you at all times and for 4 months after your last injection of Yuflyma
- Show this card to any doctor or health care professional that you see
- Record information about any tuberculosis tests or treatment you have had on the back of this card.



▼ Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il> In addition, you can report to Padagis through the following address: Padagis.co.il

The information card was approved by the Ministry of Health in July 2023.



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

Tuberculosis (TB) Tests and Treatment

Mark this box if you have ever **been tested for TB:**

Yes (check with your doctor if you do not know)

Mark this box if you have ever **had any test that was positive for TB:**

Yes (check with your doctor if you do not know)

Mark this box if you have ever **taken any medicines to treat or prevent TB:**

Yes (check with your doctor if you do not know)

Please read the Yuflyma package leaflets for more information.

If you have any other questions, talk to your doctor or another health care professional.

Your name:

Doctor's name
(who prescribed Yuflyma):

Doctor's phone number:

Date of your first Yuflyma injection:

Dose of your Yuflyma injection:

Date of your last Yuflyma injection
(if no longer taking Yuflyma):

Please fill out this information for you and health care professionals involved in your medical care or treatment.

Yuflyma is a biosimilar preparation. For further information on biosimilars, refer to the Ministry of Health website:

<https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx>

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 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 doctor about any health problems you have and any medicines you take. This will help you and your doctor decide if Yuflyma is right for you.

Tell your doctor if:

- You have an infection or

have symptoms of an infection (such as fever, wounds, feeling tired, dental problems)

- You have tuberculosis or have been in close contact with someone with tuberculosis
- You have or have had cancer
- You have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis

Your doctor should check you for signs and symptoms of tuberculosis before starting Yuflyma. You may need to be treated for tuberculosis before you start Yuflyma.

Vaccinations

- You may receive vaccinations, except for live vaccines.
- If you receive Yuflyma while you are pregnant, it is important that you inform your baby's doctor before your baby receives any vaccine. Your baby should not receive a 'live vaccine', such as BCG (used to prevent tuberculosis) within 5 months following your last Yuflyma injection during pregnancy.

During Yuflyma treatment

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

Keep your doctor informed about how Yuflyma is working for you.

- It is important to call your doctor right away about any unusual symptoms you may have. This will help make sure you get 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 doctor right away.

- If you get a side effect, your doctor will decide if you should continue or stop your Yuflyma treatment. It is important to talk with your doctor to find out what is right for you.
- Since side effects can happen after your last dose of Yuflyma, tell your doctor about any problems that you may have up to 4 months after your last injection of Yuflyma.

Tell your doctor about:

- Any new medical conditions that you have
- New medicines you are taking
- Any surgery or operation that you have planned

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 you more likely to get infections or make any infection that you may have worse. This includes infectious such as colds or more serious infections like tuberculosis.

Cancer

- If you take 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 Yuflyma.

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 doctor or get medical care right away if you have 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), diarrhea, 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) you already have; severe itchiness that cannot be explained.

Nervous system problems

- Numbness or tingling, vision changes, muscle weakness, unexplained dizziness.

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