

Patient reminder card

The patient reminder card contains important safety information that a patient needs to be aware of before and during the treatment with Yuflyma. This reminder card is helpful to the patient as it highlights the risk of serious infections, tuberculosis (TB), malignancies, demyelinating disorders (including multiple sclerosis [MS], Guillain Barré syndrome [GBS] and optic neuritis [ON]) and BCG disease following live BCG vaccination in infants with in utero exposure to Yuflyma. The key messages of patient reminder card have been provided below:

Call your/your child's doctor or get medical care right away, if you/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, muscle weakness, unexplained dizziness

For Adult Patients

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);
- Have tuberculosis or have been in close contact with someone with tuberculosis;
- Have or have had cancer;
- Have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis;
- Reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic.

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.

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

Your name: _____

Doctor's name (who prescribed Yuflyma): _____

Doctor's phone number: _____

Indication: _____

Date of your first Yuflyma injection: _____

Dose of your Yuflyma injection: _____

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

Tuberculosis (TB) Tests

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

Tuberculin test: _____

Chest X-ray: _____

For Paediatric Patients

Before Yuflyma 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 Yuflyma is right for your child.

Tell your child's doctor if your child:

- Has an infection or has 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;
- Resides in or travels to regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic.

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

Vaccinations

- 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 your child'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 his or her doctor regularly to discuss how your child is doing. Tell your 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 his or her 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;

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 Yuflyma): _____

Your child's doctor's phone number: _____

Indication: _____

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): _____

Tuberculosis (TB) Tests

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

Tuberculin test: _____

Chest X-ray: _____

Please report any suspected adverse reactions to Yuflyma to Hikma Pharmaceuticals at SAPV@hikma.com and/or to the SFDA on the following contact details: e-mail: npc.drug@sFDA.com, Website: <https://ade.sFDA.gov.sa>, Call center number: 19999, or QR Code:

