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Yuflyma (*adalimumab*)

An overview of Yuflyma and why it is authorised in the EU

What is Yuflyma and what is it used for?

Yuflyma is a medicine that acts on the immune system (the body's natural defences) and is used to treat the following conditions:

- plaque psoriasis (a disease causing red, scaly patches on the skin);
- psoriatic arthritis (a disease causing red, scaly patches on the skin with inflammation of the joints);
- rheumatoid arthritis (a disease causing inflammation of the joints);
- polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis (both rare diseases causing inflammation in the joints);
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and when there are clear signs of inflammation but X-ray does not show disease;
- Crohn's disease (a disease causing inflammation of the gut);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- hidradenitis suppurativa (acne inversa), a chronic skin disease that causes lumps, abscesses (collections of pus) and scarring on the skin;
- non-infectious uveitis (inflammation of the layer beneath the white of the eyeball).

Yuflyma is mostly used in adults when their condition is severe, moderately severe or getting worse, or when patients cannot use other treatments. For more information on the use of Yuflyma in all conditions, including when it can be used in children, see the package leaflet or contact your doctor or pharmacist.

Yuflyma is a 'biosimilar medicine'. This means that Yuflyma is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Yuflyma is Humira. For more information on biosimilar medicines, see here.

Yuflyma contains the active substance adalimumab.

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How is Yuflyma used?

Yuflyma is available in a pre-filled syringe or pen and is given as an injection under the skin, usually every 2 weeks. The dose and frequency of injections depend on the condition being treated and the dose for a child is usually calculated according to the child's weight. After training, patients or their carers may inject Yuflyma if their doctor considers it appropriate.

Yuflyma can only be obtained with a prescription and treatment must be started and supervised by a doctor who has experience in the treatment of the diseases for which Yuflyma is used. Eye specialists treating uveitis should also take advice from doctors who have experience of using adalimumab.

For more information about using Yuflyma, see the package leaflet or contact your doctor or pharmacist.

How does Yuflyma work?

The active substance in Yuflyma, adalimumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a substance in the body called tumour necrosis factor (TNF). TNF is involved in causing inflammation and is found at high levels in patients with the diseases that Yuflyma is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

What benefits of Yuflyma have been shown in studies?

Laboratory studies comparing Yuflyma with Humira have shown that the active substance in Yuflyma is highly similar to that in Humira in terms of structure, purity and biological activity. Studies have also shown that giving Yuflyma produces similar levels of the active substance in the body to giving Humira.

In addition, a study involving 648 patients with moderate to severe rheumatoid arthritis has shown that Yuflyma was as effective as Humira in reducing symptoms of the disease when given with methotrexate. After 24 weeks, the proportion of patients with at least a 20% improvement in symptom score (called ACR20) was 83% (268 of 324 patients) with both medicines.

Because Yuflyma is a biosimilar medicine, the studies on effectiveness and safety of adalimumab carried out with Humira do not all need to be repeated for Yuflyma.

What are the risks associated with Yuflyma?

For the full list of side effects and restrictions with Yuflyma, see the package leaflet.

The safety of Yuflyma has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Humira.

The most common side effects with adalimumab (which may affect more than 1 in 10 people) are infections (including in the nose, throat and sinuses), injection site reactions (redness, itching, bleeding, pain or swelling), headache and muscle and bone pain. Like other medicines of its class, Yuflyma may affect the ability of the immune system to fight off infections and cancer, and there have been some cases of serious infections and blood cancers in patients using adalimumab.

Other rare serious side effects of adalimumab (which may affect up to 1 in 1,000 people) include failure of the bone marrow to produce blood cells, disorder of the nerves, lupus and lupus-like conditions (where the immune system attacks the patient's own tissues, causing inflammation and

organ damage), and Stevens-Johnson syndrome (a life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals).

Yuflyma must not be used in patients with active tuberculosis or other severe infections, or in patients with moderate to severe heart failure (an inability of the heart to pump enough blood around the body).

Why is Yuflyma authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Yuflyma has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way. In addition, studies in patients with rheumatoid arthritis have shown that the safety and effectiveness of Yuflyma is equivalent to that of Humira.

All these data were considered sufficient to conclude that Yuflyma will behave in the same way as Humira in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Humira, the benefits of Yuflyma outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Yuflyma?

Patients treated with Yuflyma must be given a reminder card with information on the safety of the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Yuflyma have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Yuflyma are continuously monitored. Side effects reported with Yuflyma are carefully evaluated and any necessary action taken to protect patients.

Other information about Yuflyma

Yuflyma received a marketing authorisation valid throughout the EU on 11 February 2021.

Further information on Yuflyma can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/yuflyma.

This overview was last updated in 12-2023.