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Hefiya (*adalimumab*)

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

What is Hefiya and what is it used for?

Hefiya is a medicine that acts on the immune system 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);
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and when X-ray does not show disease but there are clear signs of inflammation;
- polyarticular juvenile idiopathic arthritis and active enthesitis-related arthritis (both rare diseases causing inflammation in the joints);
- 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 long-term 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).

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

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

How is Hefiya used?

Hefiya is available as a solution for injection under the skin in a pre-filled syringe or pen and is usually

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given every 2 weeks. The dose and frequency of injection depends on the condition to be treated and the dose for a child is usually calculated according to the child's weight; because Hefiya is only available in doses of 40 mg, it is not suitable for children who need less than a 40-mg dose. After training, patients or their carers may inject Hefiya if their doctor considers it appropriate.

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

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

How does Hefiya work?

The active substance in Hefiya, 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 Hefiya is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

What benefits of Hefiya have been shown in studies?

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

In addition Hefiya was as effective as Humira in a study involving 465 patients with moderate or severe plaque psoriasis. The proportion of patients who had at least a 75% reduction in symptoms after 16 weeks of treatment was 68% with Hefiya and 63% with Humira.

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

What are the risks associated with Hefiya?

The most common side effects with adalimumab (seen in more than 1 patient in 10) 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, Hefiya 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 (which may affect up to 1 in 1,000 people) include failure of 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 (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals).

Hefiya 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).

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

Why is Hefiya authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Hefiya has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way.

In addition, a study in psoriasis has shown that the effects of the medicine are equivalent to those of Humira in this condition. All these data were considered sufficient to conclude that Hefiya will behave in the same way as Humira in terms of effectiveness and safety in its approved uses. Therefore, the Agency's view was that, as for Humira, the benefit of Hefiya outweighs the identified risk and it can be authorised.

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

Patients treated with Hefiya 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 Hefiya have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Hefiya

Hefiya received a marketing authorisation valid throughout the EU on 26 July 2018.

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

This overview was last updated in 07-2019.