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Hyrimoz (*adalimumab)*

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

What is Hyrimoz and what is it used for?

Hyrimoz 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).

Hyrimoz 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 Hyrimoz in all conditions, including when it can be used in children, see the package leaflet or contact your doctor or pharmacist.

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

How is Hyrimoz used?

Hyrimoz is available as a solution for injection under the skin,

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usually given every 2 weeks. The dose and frequency of injection depends on the condition to be treated and the dose for a child is calculated according to the child's weight. After training, patients or their carers may inject Hyrimoz if their doctor considers it appropriate.

Hyrimoz 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 Hyrimoz is used. Eye specialists treating uveitis should also take advice from doctors who have experience of using Hyrimoz.

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

How does Hyrimoz work?

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

What benefits of Hyrimoz have been shown in studies?

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

In addition, Hyrimoz 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 Hyrimoz and 63% with Humira.

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

What are the risks associated with Hyrimoz?

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, Hyrimoz 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).

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

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

Why is Hyrimoz authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Hyrimoz 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 Hyrimoz 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 benefits of Hyrimoz outweigh the identified risks and it can be authorised.

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

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

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

Other information about Hyrimoz

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

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

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