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Libmyris (*adalimumab*)

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

What is Libmyris and what is it used for?

Libmyris 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).

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

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

Libmyris contains the active substance adalimumab.

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How is Libmyris used?

Libmyris is available for injection under the skin in a pre-filled syringe or pen and is usually given every 2 weeks. The dose and frequency of injection depend on the condition to be treated and the dose for a child is usually calculated according to the child's weight; because Libmyris is only available in doses of 40 or 80 mg, it is not suitable for children who need less than a 40-mg dose. After training, patients or their carers may inject Libmyris if their doctor considers it appropriate.

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

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

How does Libmyris work?

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

What benefits of Libmyris have been shown in studies?

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

In addition, a study involving 412 adult patients with plaque psoriasis has shown that Libmyris was as effective as Humira in controlling the disease; average scores measuring the extent and severity of the condition improved by 91% after 16 weeks of treatment with either medicine.

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

What are the risks associated with Libmyris?

The safety of Libmyris 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, Libmyris 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 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).

Libmyris 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 Libmyris, see the package leaflet.

Why is Libmyris authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Libmyris 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 adults with plaque psoriasis have shown that the safety and effectiveness of Libmyris is equivalent to that of Humira in this group.

All these data were considered sufficient to conclude that Libmyris 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 Libmyris 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 Libmyris?

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

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

Other information about Libmyris

Libmyris received a marketing authorisation valid throughout the EU on 12 November 2021.

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

This overview was last updated in 11-2021.