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EPAR summary for the public

Lifmior

etanercept

This is a summary of the European public assessment report (EPAR) for Lifmior. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lifmior.

For practical information about using Lifmior, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lifmior and what is it used for?

Lifmior is an anti-inflammatory medicine for treating the following diseases:

- rheumatoid arthritis (a disease causing inflammation of the joints) alone or with methotrexate in adults
- certain forms of juvenile idiopathic arthritis (inflammation of joints in children and adolescents)
- plaque psoriasis (a disease causing red, scaly patches on the skin) in adults and children
- psoriatic arthritis (psoriasis with inflammation of the joints) in adults
- ankylosing spondylitis (a disease causing inflammation of the joints of the spine) in adults
- axial spondyloarthritis (a chronic inflammatory disease of the spine) in adults when there are no abnormalities seen on x-ray.

Lifmior is mostly used when these conditions are severe or moderately severe, or when other treatments have not worked well enough. For detailed information on the use of Lifmior in all conditions, see the summary of product characteristics (also part of the EPAR).

Lifmior is identical to Enbrel, which has been authorised in the EU since 3 February 2000. It contains the active substance etanercept.

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How is Lifmior used?

Lifmior is given as an injection under the skin. In adults, the usual recommended dose is 25 mg twice a week or 50 mg once a week. In children, the dose will depend on body weight. The patient or carer can give the injection if they have been trained appropriately. For more information, see the package leaflet.

The medicine can only be obtained with a prescription. Treatment is started and supervised by specialised doctors with experience in diagnosing and treating the diseases Lifmior is used for.

How does Lifmior work?

The active substance in Lifmior, etanercept, is a protein that has been designed to block the activity of a substance called tumour necrosis factor (TNF). This substance is involved in causing inflammation and is found at high levels in patients with the diseases that Lifmior is used to treat. By blocking TNF, etanercept reduces the inflammation and other symptoms of the diseases.

What benefits of Lifmior have been shown in studies?

Several studies have shown that Lifmior is more effective at reducing symptoms of inflammatory conditions than placebo (a dummy treatment) or a comparator medicine.

In rheumatoid arthritis, five studies have been carried out involving around 2,200 patients. Three of these studies in patients who had taken arthritis medicines in the past showed about two-thirds of the patients who received Lifmior had a reduction in symptoms of 20% or more after three months based on a standard rating score (ACR 20). This compared with around a quarter of the patients receiving placebo.

In a fourth study of rheumatoid arthritis patients who had not taken methotrexate before, those receiving 25 mg Lifmior twice a week had less joint damage than those taking methotrexate alone after 12 and 24 months. A fifth study showed that Lifmior on its own or in combination with methotrexate was more effective than methotrexate alone.

Further studies have been carried out in over 2,300 patients with other inflammatory diseases (juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and axial spondyloarthritis). These studies also showed that Lifmior produced a greater improvement in symptoms than placebo after three to four months using various standard rating scores such as ACR, ASAS and PASI.

What is the risk associated with Lifmior?

The most common side effects with Lifmior (seen in more than 1 patient in 10) are injection site reactions (including bleeding, bruising, redness, itching, pain and swelling) and infections (including colds, and lung, bladder and skin infections). Patients developing a serious infection should stop Lifmior treatment. For the full list of all side effects reported with Lifmior, see the package leaflet.

Lifmior must not be used in patients who have or are at risk of sepsis (when bacteria and toxins circulate in the blood and start to damage the organs), or in patients with infections. For the full list of restrictions, see the package leaflet.

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Why is Lifmior approved?

Lifmior is effective at reducing symptoms in several inflammatory conditions and its side effects are considered manageable. The CHMP therefore concluded that Lifmior's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that markets Lifmior will provide educational material for doctors expected to prescribe the product to teach patients how to use the pre-filled pen correctly and a special alert card for patients so they can recognise serious side effects and know when to seek urgent attention from their doctor.

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

Other information about Lifmior

The European Commission granted a marketing authorisation valid throughout the European Union for Lifmior on 13 February 2017.

The full EPAR for Lifmior can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Lifmior, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.

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