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EPAR summary for the public

Erelzi

etanercept

This is a summary of the European public assessment report (EPAR) for Erelzi. 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 Erelzi.

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

What is Erelzi and what is it used for?

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

- rheumatoid arthritis (a disease causing inflammation of the joints) in adults, used with another medicine, methotrexate, or alone;
- certain forms of juvenile idiopathic arthritis (diseases causing inflammation in the joints, with first appearance in childhood or adolescence);
- 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 and adolescents;
- 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.

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



Erelzi contains the active substance etanercept and is a 'biosimilar medicine'. This means that Erelzi is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Erelzi is Enbrel. For more information on biosimilar medicines, see [here](#).

How is Erelzi used?

Erelzi is available as prefilled syringes and pens containing a solution for injection. The injection is given under the skin and the patient or their carer can give the injection if they have been trained appropriately. In adults, the usual recommended dose is 25 mg twice a week or 50 mg once a week. Treatment with 50 mg twice a week can also be used during the first 12 weeks of treatment for plaque psoriasis. In children, the dose will depend on body weight. Erelzi is not for use in children who need doses other than 25 or 50 mg (e.g. those weighing less than 62.5 kg), because it is only available in these doses; an alternative product should be used in such children. 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 Erelzi is used for.

How does Erelzi work?

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

What benefits of Erelzi have been shown in studies?

Laboratory studies comparing Erelzi with Enbrel have shown that the active substance in Erelzi is highly similar to that in Enbrel in terms of structure, purity and biological activity.

Because Erelzi is a biosimilar medicine, the studies on effectiveness and safety of etanercept carried out with Enbrel do not all need to be repeated for Erelzi. Studies were carried out to show that Erelzi produces similar levels of the active substance in the body to Enbrel.

Erelzi was also shown to be as effective as Enbrel in one main study involving 531 adults with plaque psoriasis. Over 70% of those given Erelzi (186 of 264 patients) and roughly 72% of those given Enbrel (191 of 267) had at least 75% reduction in their symptom score after 12 weeks of treatment, which was the main measure of effectiveness.

What are the risks associated with Erelzi?

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

Erelzi 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 active infections. For the full list of restrictions, see the package leaflet.

Why is Erelzi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Erelzi has been shown to have a comparable quality, safety and effectiveness to Enbrel. Therefore, the CHMP's view was that, as for Enbrel, the benefit outweighs the identified risk. The Committee recommended that Erelzi be given marketing authorisation.

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

The company that markets Erelzi 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. The educational materials also include a reminder that Erelzi is not for use in children and adolescents who weigh less than 62.5 kg.

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

Other information about Erelzi

The European Commission granted a marketing authorisation valid throughout the European Union for Erelzi on 23 June 2017.

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

This summary was last updated in 06-2017.