



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Erelzi (*etanercept*)

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

What is Erelzi and what is it used for?

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

- rheumatoid arthritis (a disease causing inflammation of the joints), used with another medicine, methotrexate, or alone;
- certain forms of juvenile idiopathic arthritis (diseases causing inflammation in the joints);
- plaque psoriasis (a disease causing red, scaly patches on the skin);
- psoriatic arthritis (psoriasis with inflammation of the joints);
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and non-radiographic axial spondyloarthritis which is when there are clear signs of inflammation but X-ray does not show disease.

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 package leaflet or contact your doctor or pharmacist.

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

How is Erelzi used?

Erelzi is available for injection under the skin. The patient or the patient's carer can give the injection after appropriate training. 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 depends 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

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only available in these strengths; an alternative etanercept medicine 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 that Erelzi is used for. For more information about using Erelzi, see the package leaflet or contact your doctor or pharmacist.

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.

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 nose, throat, lung, bladder and skin infections). The doctor may stop Erelzi treatment in patients developing a serious infection. For the full list of side effects of 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 authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Erelzi has a highly similar structure, purity and biological activity to Enbrel and is distributed in the body in the same way. In addition, studies have shown that the safety and effectiveness of Erelzi is equivalent to that of Enbrel in plaque psoriasis.

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

The company that markets Erelzi will provide a card for patients that contains information on how to recognise serious side effects and know when to see their doctor urgently. 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.

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

Other information about Erelzi

Erelzi received a marketing authorisation valid throughout the EU for Erelzi on 23 June 2017.

Further information can be found on the Agency's website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/erelzi>.

This summary was last updated in 11-2020.