EMA/167604/2020
EMEA/H/C/004711

Nepexto (*etanercept*)

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

What is Nepexto and what is it used for?

Nepexto 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 (a disease causing red, scaly patches on the skin 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.

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

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

Nepexto contains the active substance etanercept.

How is Nepexto used?

Nepexto can only be obtained with a prescription and is available for injection under the skin. Treatment should be started and supervised by a doctor with experience in diagnosing and treating the conditions that Nepexto is used for; the patient or their carer can give the injection if they have been trained to do so.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 be used during the first 12 weeks of treatment for plaque psoriasis. In children, the dose will depend on body weight. Nepexto is not for use in children whose body weight means that they need doses other than 25 or 50 mg, since it is only available in these doses; an alternative product should be used in such children.

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

How does Nepexto work?

The active substance in Nepexto, 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 Nepexto is used to treat. By blocking TNF, etanercept reduces inflammation and other symptoms of the diseases.

What benefits of Nepexto have been shown in studies?

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

In addition, Nepexto was considered to be as effective as Enbrel in one main study involving 517 patients with moderate to severe rheumatoid arthritis. After treatment for 24 weeks, around 81% of patients treated with Nepexto had at least a 20% decrease in symptoms of rheumatoid arthritis, compared with 87% of those treated with Enbrel.

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

What are the risks associated with Nepexto?

The safety of Nepexto 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 Enbrel.

The most common side effects with etanercept (which may affect more than 1 in 10 people) are injection-site reactions (including bleeding, redness, itching, pain and swelling) and infections (including colds, and lung, bladder and skin infections). For the full list of side effects of Nepexto, see the package leaflet.

Nepexto must not be started in patients with active infections or 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). Patients developing a serious infection should stop Nepexto treatment. For the full list of restrictions, see the package leaflet.

Why is Nepexto authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Nepexto 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 Nepexto is equivalent to that of Enbrel in rheumatoid arthritis.

All these data were considered sufficient to conclude that Nepexto will behave in the same way as Enbrel in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Enbrel, the benefits of Nepexto 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 Nepexto?

The company that markets Nepexto will provide educational material for doctors expected to prescribe the medicine, to help them teach patients how to use it correctly and remind them not to use the medicine in children and adolescents whose body weight is less than 62.5 kg. It will also provide 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 Nepexto have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Nepexto

Nepexto received a marketing authorisation valid throughout the EU on 20 May 2020.

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

This overview was last updated in 05-2020.