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Fubelv (*etanarcept*)

A plain-language overview of Fubelv and why it is authorised in the EU

What is Fubelv and what is it used for?

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

- rheumatoid arthritis (a disease causing inflammation of the joints); it is used alone or with another medicine called methotrexate;
- certain forms of juvenile idiopathic arthritis (a childhood disease causing inflammation of 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.

Fubelv is mostly used when these conditions are severe or moderately severe, or when other treatments have not worked well enough or cannot be used. It is used in adults and, for some conditions, in children. For detailed information on the use of Fubelv in all conditions, see the package leaflet or contact your doctor or pharmacist.

Fubelv contains the active substance etanarcept and is a biological medicine. It is a 'biosimilar medicine'; this means that Fubelv is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Fubelv is Enbrel. For more information on biosimilar medicines, see here.

How is Fubelv used?

Fubelv can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in diagnosing and treating the diseases it is used for.

Fubelv is given by injection under the skin. In adults, the medicine is injected once or twice a week. In children, it is injected every 3 to 4 days or once a week. Some children may require a dose that Fubelv does not provide; in such cases, another etanarcept medicine that offers an appropriate dose should be used.

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Patients or their caregivers may inject Fubelv once they have been trained, if their doctor thinks that this is appropriate.

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

How does Fubelv work?

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

What benefits of Fubelv have been shown in studies?

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

In addition, Fubelv was shown to be as effective as Enbrel in a main study involving 517 adults with moderate to severe rheumatoid arthritis who were being treated with methotrexate. The main measure of effectiveness was the number of patients with at least a 20% reduction in the number of tender and swollen joints, together with improvement in other symptoms of rheumatoid arthritis such as pain, signs of inflammation and the ability of the patient to carry out daily activities.

After about 6 months of treatment, Fubelv was found to be effective at reducing symptoms of rheumatoid arthritis in approximately 81% of patients, and Enbrel was effective in about 87% of patients.

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

Studies carried out with Fubelv are described in more detail in the medicine’s assessment report.

What are the side effects and restrictions with Fubelv?

The safety of Fubelv has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Enbrel.

For the full list of side effects and restrictions of Fubelv, see the package leaflet.

The most common side effects with Fubelv (which may affect more than 1 in 10 people) include reactions at the injection site (such as bleeding, bruising, redness, itching, pain and swelling) and infections of the nose and throat, lungs, bladder and skin.

Fubelv must not be used in people who have or are at risk of sepsis (when bacteria and toxins circulate in the blood leading to organ damage), or in people who have an active infection.

Why is Fubelv authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Fubelv has a highly similar structure, purity and biological activity to Enbrel and is distributed in the body in the same way.

In addition, a study has shown that Fubelv and Enbrel are equivalent in terms of safety and effectiveness in rheumatoid arthritis.

All these data were considered sufficient to conclude that Fubelv will have the same effects as Enbrel in its authorised uses. Therefore, the Agency's view was that, as for Enbrel, the benefits of Fubelv 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 Fubelv?

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

This patient card will be made available by national competent authorities on their websites. A list of these national resources is available on the EMA website.

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

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

Other information about Fubelv

Fubelv received a marketing authorisation valid throughout the EU on 23 April 2026.

Further information on Fubelv, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/fubelv.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 04-2026.