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Spevigo (*spesolimab*)

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

What is Spevigo and what is it used for?

Spevigo is a medicine that acts on the immune system. It is used in adults and adolescents from 12 years of age to prevent and treat flare-ups (recurrence or worsening) of generalised pustular psoriasis, an inflammatory skin disease causing pustules (pus-filled lesions) to appear over large areas of skin.

Spevigo contains the active substance spesolimab.

How is Spevigo used?

Spevigo can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in managing patients with inflammatory skin diseases.

When used to prevent flare-ups, Spevigo is injected under the skin of the upper thigh or abdomen (belly) every four weeks, using a pre-filled syringe. Patients and carers can inject the medicines themselves after receiving appropriate training.

When used to treat flare-ups, the medicine is given once as an infusion (drip) into a vein over 90 minutes; a second dose can be given one week later if symptoms are still present.

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

How does Spevigo work?

The active substance in Spevigo, spesolimab, is a monoclonal antibody (a type of protein) that binds to and blocks the receptor (target) for a protein involved in inflammation called interleukin-36 (IL-36). By preventing IL-36 from attaching to its receptor, Spevigo reduces inflammation and improves the symptoms of generalised pustular psoriasis.

What benefits of Spevigo have been shown in studies?

A main study involving 53 adults with generalised pustular psoriasis flare-ups of moderate to severe intensity showed that Spevigo was more effective than placebo (a dummy treatment) at improving symptoms of the disease. After one week, 54% (19 out of 35 patients) of those who received a single

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dose of Spevigo had no visible pustules compared with 6% (1 out of 18 patients) of those who were given placebo, as measured using the GPPGA pustulation subscore (a measure of the severity of the pustules).

Another main study involved 123 adults and adolescents with a history of generalised pustular psoriasis. Over 48 weeks of treatment, 10% (3 out of 30) of patients using Spevigo had one or more flare-ups, compared with 52% (16 out of 31) of patients on placebo.

What are the risks associated with Spevigo?

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

The most common side effects with Spevigo (which may affect more than 1 in 10 people) are infections.

Spevigo must not be given to patients who have an active infection that the doctor considers important.

Why is Spevigo authorised in the EU?

The severity of generalised pustular psoriasis flare-ups varies but can lead to organ failure and sepsis (blood poisoning). The disease is therefore a considerable burden on patients' lives. At the time of approval, there were no approved treatments for flare-ups of generalised pustular psoriasis and most therapies used in clinical practice had limited data on safety and efficacy.

Spevigo has been shown to be effective at preventing flare-ups and at clearing pustules within one week following a flare-up. Although safety data are limited, the safety profile is considered manageable.

Spevigo has been given 'conditional authorisation'. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Spevigo. It must submit data from a study of the medicine in the treatment of recurrent flare-ups in patients with generalised pustular psoriasis to confirm its safety and effectiveness. Every year, the Agency will review any new information that becomes available.

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

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

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

Other information about Spevigo

Spevigo received a conditional marketing authorisation valid throughout the EU on 9 December 2022.

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

This overview was last updated in 08-2024.