swissmedic

Summary report on authorisation dated 10 October 2025

Spevigo® (active substance: spesolimab)

Indication extension in Switzerland: 28 May 2025

Solution for injection in a pre-filled syringe for the prevention of flare-ups of generalised pustular psoriasis in adults and adolescents aged 12 years or older

About the medicinal product

The medicinal product Spevigo, containing the active substance spesolimab, is used for the prevention of flare-ups in adults and adolescents aged 12 years or older with generalised pustular psoriasis (GPP).

Generalised pustular psoriasis is a rare but severe skin disorder. It manifests in recurring flare-ups. Widespread, painful, severe redness and pustules form, often accompanied by systemic inflammation that manifests in fatigue and high fever. Severe GPP flare-ups can lead to multiple organ failure and sepsis (blood poisoning).

Spevigo was first granted temporary authorisation by Swissmedic on 9 August 2023 for the treatment of flare-ups of generalised pustular psoriasis (GPP) in adult patients. The treatment was administered directly into the vein via an infusion.

This indication extension means that Spevigo can now be used for the prevention of flare-ups in adults and adolescents aged 12 years or older with generalised pustular psoriasis (GPP). The treatment is administered subcutaneously using pre-filled syringes.

Mode of action

The active substance spesolimab is a monoclonal antibody.

Monoclonal antibodies are immunologically active proteins that can bind specifically to other proteins, e.g. receptors. Spesolimab blocks the interleukin-36 (IL-36) receptor. When activated, this receptor triggers inflammatory responses. By blocking this receptor, Spevigo helps reduce the symptoms and prevent the occurrence of new flare-ups.

Administration

Spevigo, containing the active substance spesolimab, is a prescription-only medicine and is administered subcutaneously (under the skin) as a solution for injection in a pre-filled syringe.

Spevigo is available in pre-filled syringes. Each syringe contains 150 mg of the active substance spesolimab. The recommended starting dose consists of a single injection of 600 mg in total (4 pre-filled syringes), followed by a dose of 300 mg (2 pre-filled syringes) every 4 weeks.

Efficacy

The efficacy of Spevigo was investigated in the Effisayil 2 study. 123 patients aged from 12 to 75 with generalised pustular psoriasis (GPP) took part in this trial. The patients were divided into four groups. Three groups received different dosages of Spevigo, while one group received a placebo (dummy drug). The time to the first flare-up within 48 weeks was assessed. In the group receiving the authorised dose of Spevigo, 10% of the patients experienced a flare-up compared to 51.6 % in the group receiving placebo.

Precautions, undesirable effects, & risks

Spevigo must not be used in those who are hypersensitive to the active substance or any of the excipients. Severe hypersensitivity reactions (DRESS) occurred in the clinical trials with Spevigo.

The most common undesirable effects (affecting more than 1 in 10 of those treated) are redness of the skin at the injection site and increased susceptibility to infection with pathogens such as viruses, bacteria and fungi.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

GPP is a rare skin disorder that can have potentially fatal consequences. No medicinal product for the prevention of flare-ups of GPP has been authorised in Switzerland to date. There is therefore a great medical need for treatment options.

The study showed that Spevigo produces a significant reduction in the frequency of GPP flare-ups compared to placebo.

Taking all the risks and precautions into account, and based on the available data, the benefits of Spevigo outweigh the risks. Swissmedic has therefore authorised the medicinal product Spevigo, containing the active substance spesolimab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Spevigo®

Information for patients (package leaflet): Information for patients Spevigo®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.