swissmedic

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Spevigo® (active substance: spesolimab)

First authorisation in Switzerland: 9 August 2023

Medicinal product (solution for infusion) for treatment of generalised pustular psoriasis in adults

About the medicinal product

The medicinal product Spevigo, containing the active substance spesolimab, has been granted temporary authorisation for the treatment of flare-ups of generalised pustular psoriasis (GPP) in adults.

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).

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 the receptor with spesolimab, these inflammatory responses are suppressed and GPP symptoms are reduced.

Administration

Spevigo, containing the active substance spesolimab, is a prescription-only medicine and is administered as an infusion into a vein.

Spevigo is a concentrate for solution for infusion available in vials containing 7.5 mL with 450 mg spesolimab. The recommended single dose is 900 mg. If symptoms of the flare-up persist, a further dose of 900 mg can be administered 1 week after the first dose.

Efficacy

The efficacy of Spevigo was investigated in a study with 53 GPP patients aged between 21 and 69 years, of whom 68% were women. The GPP patients, who had mild to severe

flare-ups, were allocated to either the Spevigo group (35 people) or the placebo group, who received a dummy drug (18 people). On the first day, the patients received either Spevigo or the placebo as a single dose. If their condition worsened after Day 1, the patients also received a standard treatment chosen by the doctor. Visible pustule formation was assessed. One week after administration, 54% of the Spevigo group had no visible pustule formation, compared with 6% of the placebo group.

Precautions, undesirable effects, & risks

Spevigo must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effect is increased susceptibility to infection with pathogens such as viruses, bacteria and fungi. This affects more than 1 in 10 users.

All precautions, risks, and other possible undesirable effects are listed in 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 treatment of GPP has been authorised in Switzerland to date. There is therefore a great medical need for treatment options. Spevigo has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

The efficacy of Spevigo for GPP was proven in the study. The data required to fully assess the safety of Spevigo are not yet complete. There is a lack of long-term data. In addition, there are still some uncertainties regarding dosage for recurring flare-ups and the body's immunological response to the medicinal product. These will be clarified in further studies.

Taking all the risks and precautions into account, and based on the available data, the benefits of Spevigo outweigh the risks. Swissmedic has authorised the medicinal product Spevigo, containing the active substance spesolimab, temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation if the benefit-risk assessment of the results remains positive.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals 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 Public Summary SwissPAR.

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.