

Spevigo[®] (spesolimab-sbzo) – Expanded indication

- On March 19, 2024, [Boehringer Ingelheim](#) announced the FDA approval of [Spevigo \(spesolimab-sbzo\)](#), for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.
 - Spevigo was previously approved in adults and only for treatment of GPP flares.
- In addition to the expanded indication, the FDA approved a 150 mg/mL solution in a single-dose prefilled syringe formulation of Spevigo for subcutaneous (SC) administration. Spevigo was previously approved for intravenous (IV) use only.
- The approval of Spevigo for the expanded indication was based on a randomized, double-blind, placebo-controlled study (Study Effisayil-2) in adults and pediatric subjects (12 years of age and older and weighing at least 40 kg) with a history of at least two GPP flares of moderate-to-severe intensity in the past. Patients were randomized to one of four treatment arms, including three different regimens for Spevigo and one placebo arm. The results below are only for the recommended dosage regimen. The primary endpoint was the time to the first GPP flare up to week 48.
 - The percentage of patients with a GPP flare was 10% with Spevigo vs. 52% with placebo (risk difference -39, 95% CI: -62, -16).
- The most common adverse reactions with Spevigo use for treatment of GPP in patients not experiencing a flare were injection site reaction, urinary tract infection, arthralgia, and pruritus.
- The recommended dose of Spevigo for the treatment of GPP when not experiencing a flare is a loading dose of 600 mg (four 150 mg injections) followed by 300 mg (two 150 mg injections) administered SC 4 weeks later and every 4 weeks thereafter.
 - Four weeks after treatment of a GPP flare with IV Spevigo, Spevigo SC should be initiated or reinitiated for treatment of GPP at a dose of 300 mg (two 150 mg injections) administered every 4 weeks. A SC loading dose is not required following treatment of a GPP flare with IV Spevigo.
 - If required, the 600 mg SC loading dose of Spevigo is to be administered by a healthcare professional. For subsequent 300 mg doses, if the healthcare professional determines that it is appropriate, a patient 12 years of age and older may self-inject or the caregiver may administer Spevigo after proper training in SC injection technique.
 - Refer to the Spevigo drug label for dosing for acute treatment of GPP flares.