Spevigo®
(spesolimab-sbzo) injection

SPEVIGO Patient Support Program
Fax: 855-237-0134
Phone: 833-SPEVIGO (833-773-8446)
Email: Program@SpevigoPatientSupport.com

Instructions: All fields required unless otherwise noted. Complete entire form and **fax pages 1-3** to **855-237-0134**.
For assistance call 833-SPEVIGO, Monday-Friday 8:00 AM - 8:00 PM ET.

1 Patient Information (to be completed by Patient/Legal Guardian)

For patients under the age of 18 years, this must be completed by the Legal Guardian over the age of 18 years, and all contact information must align to the Legal Guardian.

Patient First Name _____ MI _____ Patient Last Name _____ ___/___/_____ Patient Date of Birth Gender: ☐ M ☐ F ☐ Not Specified

If Patient is under the age of 18: Legal Guardian First Name _____ Legal Guardian Last Name _____ ____/____/_____ Legal Guardian Date of Birth

Street Address _____ City _____ State _____ ZIP Code _____

Home Phone _____ Cell Phone _____ Email Address _____

Preferred contact: ☐ Home Phone ☐ Cell Phone Preferred language if not English: _____

Best time to contact: ☐ Morning ☐ Afternoon ☐ Evening ☐ YES, I am comfortable with the Program leaving my personal and health information on my voicemail.

Alternate Contact/Caregiver First and Last Name (Optional) _____ Alternate Contact/Caregiver Relationship to Patient (Optional) _____

Alternate Contact/Caregiver Email Address (Optional) _____ Alternate Contact/Caregiver Phone Number (Optional) _____ ☐ OK to discuss my condition, participation in the Program, and related services with my Alternate Contact/Caregiver.

Please indicate if you are interested in receiving any of the additional resources below.

If prescribed for subcutaneous use: ☐ Sharps disposal container ☐ Insulated travel bag

☐ YES, I agree to receive periodic messages from LEO Pharma and its affiliates, business partners, agents and service providers ("Partners") supporting the Program via calls and text messages at the cell phone number provided above. I understand calls or texts may be autodialed or prerecorded, are not a condition of purchase, and that messaging or data rates may apply.

☐ SPEVIGO Copay Program: By checking this box, I confirm I have commercial insurance and am not currently enrolled in any federal, state, or other government funded medical or prescription benefit programs. I have read and agree to the SPEVIGO Copay Program Terms and Conditions (See Section 10).

☐ YES, I would like to receive periodic communications via email or mail to learn more about other services, products, or special opportunities that LEO Pharma or its Partners believe may be of interest to me.

☐ **Patient Assistance Program (PAP)** – See Section 8 on page 3 for Patient Consent: SPEVIGO Patient Assistance Program

Patient/Legal Guardian Signature

SIGN HERE _____ ___/___/_____
Patient/Legal Guardian Signature (Required) Date

My signature above affirms that I have read, understand and agree to the Patient Authorization in Section 9, page 4, and that I have received a prescription for SPEVIGO.

Scan or click to learn more about **SPEVIGO.**

Sections 2-7 must be completed by a healthcare professional.

2 Patient Insurance Information (Required)

Please include copies (front and back) of the patient's medical and pharmacy insurance card(s).
If no cards are available, other forms such as the Patient Demographic Form are acceptable.

Check all that apply ☐ Primary Medical ☐ Secondary Medical ☐ Pharmacy ☐ Patient is Uninsured

3 Prescriber Information

First Name _____ Last Name _____ State Medical License _____ NPI _____

Facility Name _____ Phone _____ Fax _____

Street Address _____ City _____ State _____ ZIP Code _____ HCP Specialty _____

Office Contact Name _____ Office Contact Phone (Direct Ext.) _____ Office Contact Email Address _____

Tax ID _____

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide and Instruction for use.

Patient First Name _____ Patient Last Name _____ ___/___/_____ Date of Birth

4 Site of Care/Shipping Information*

☐ **Spevigo®** (spesolimab-sbzo) **IV Infusion for patient experiencing a flare**

Ship to: ☐ HCP ☐ Infusion Center ☐ Other

Treatment Site Name _____

Shipment Address _____

☐ **Ongoing Subcutaneous Doses** (if applicable and prescribed)

Ship to: ☐ HCP ☐ Patient

Shipment Address _____

*As allowable by law.

OR

☐ **SPEVIGO Subcutaneous Loading Dose for patients not experiencing a flare**

Ship to: ☐ HCP ☐ Infusion Center ☐ Patient ☐ Other

Treatment Site Name _____

Shipment Address _____

☐ **Ongoing Subcutaneous Doses**

Ship to: ☐ HCP ☐ Patient

Shipment Address _____

5 Clinical Information

MANDATORY

Diagnosis Code
- ☐ L40.1
- ☐ Other _____
- ☐ At least 88 lbs/40 kg

Allergies ☐ No known drug allergies

Concomitant Medications _____

Prior Therapies _____

Date of last tuberculosis test: ___/___/_____ Date or ☐ NA

TB Test Results: ☐ Positive ☐ Negative ☐ Indeterminate

6 Prescription for SPEVIGO

(To be completed by a healthcare professional and required for specialty pharmacy.)

☐ Rx has already been sent to Accredo

Subcutaneous Use for treatment of GPP when **not** experiencing a flare

Loading dose is not required following treatment with intravenous SPEVIGO within 4 weeks.

Option 1

☐ **Loading Dose: 600 mg (two 300-mg injections)**
One carton with two single-dose 300 mg/2 mL prefilled syringes (NDC: 0597-7705-72)

☐ **Loading dose already administered or not required**

Administer a subcutaneous loading dose of 600 mg (two 300-mg injections), followed by 300 mg (one 300-mg injection) subcutaneously every 4 weeks thereafter.

☐ **Ongoing Dose: 300 mg (one 300-mg injection)**
One carton containing one single-dose 300 mg/2 mL prefilled syringe (NDC 0597-7705-41)

Administer 300 mg (one 300-mg injection) subcutaneously every 4 weeks.

Refills:_____

Healthcare professional to administer loading dose. Or, loading dose is not required following treatment with intravenous SPEVIGO within 4 weeks.

Option 2

☐ **Loading Dose: 600 mg (four 150-mg injections)**
Two cartons with two single-dose 150 mg/mL prefilled syringes (NDC: 0597-0620-20)

☐ **Loading dose already administered or not required**

Administer a subcutaneous loading dose of 600 mg (four 150-mg injections), followed by 300 mg (two 150-mg injections) subcutaneously every 4 weeks thereafter.

☐ **Ongoing Dose: 300 mg (two 150-mg injections)**
One carton with two single-dose 150 mg/mL prefilled syringes (NDC: 0597-0620-20)

Administer 300 mg (two 150-mg injections) subcutaneously every 4 weeks.

Refills:_____

Intravenous Use for treatment of GPP flare

☐ **900 mg/15 mL by intravenous infusion over 90 minutes**
One carton containing two single-dose 450 mg/7.5 mL vials (NDC: 0597-0035-10)

Administer SPEVIGO as a continuous intravenous infusion through an intravenous line containing a sterile, non-pyrogenic, low-protein binding in-line filter (pore size of 0.2 micron) over 90 min. If the infusion is slowed or temporarily stopped, the total infusion time (including stop time) should not exceed 180 min.

☐ **1 Refill**

SIGN HERE

_____ ___/___/_____ OR _____ ___/___/_____

Prescriber's Signature Date Prescriber's Signature Date

***Dispense as Written**. No Stamps.* ***Substitution Permitted**. No Stamps.*

My signature above affirms that I have read, understand and agree to the Prescriber Certification.

ATTENTION: Please follow your state's specific prescription requirements (if applicable).

Prescriber Certification: By signing this form, I certify that, pursuant to the Health Insurance Portability and Accountability Act, 45 C.F.R Parts 160 and 164 ("HIPAA") and other applicable state privacy laws, I have authorization to disclose the above-named patient's Protected Health Information ("PHI") because I have obtained a legally valid HIPAA authorization and consent on file to share their PHI with LEO Pharma and its Partners. I understand that LEO Pharma will use the information within this enrollment form to administer the SPEVIGO Patient Support Program (the "Program"). The Program provides a wide array of patient-focused services, including providing logistical and non-medical treatment support for SPEVIGO as prescribed, and education about the insurance process and product. I understand that LEO Pharma may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. LEO Pharma makes no representation or guarantee concerning coverage or reimbursement for any item or service. For the purposes of transmitting this prescription, I authorize LEO Pharma and its Partners to forward for these limited purposes this prescription electronically, by facsimile, or by mail to the appropriate dispensing pharmacies.

I further understand and agree that: (a) any product or service provided through the Program as a result of this form is for the named patient only, and such product or service is not being provided in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use SPEVIGO® (spesolimab-sbzo) injection, or any other LEO Pharma product or service, for any other person; **(b)** my decision to prescribe SPEVIGO was based solely on my professional determination of medical necessity; and **(c)** I will not seek reimbursement for any product or service provided by or through the Program from any government program or third-party insurer.

I authorize LEO Pharma to act on my behalf for the limited purposes of transmitting this prescription, by any means allowed under applicable law, to the appropriate pharmacy designated by the patient utilizing their benefit plan.

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide and Instruction for use.

Patient First Name _____ Patient Last Name _____ ___/___/_____ Date of Birth

7 Spevigo® (spesolimab-sbzo) Bridge Program (OPTIONAL STEP)

SPEVIGO Bridge Program may provide a limited supply of SPEVIGO for subcutaneous use for free to eligible patients who are experiencing a coverage delay or denial. Terms and Conditions apply. See Section 10 for more information.

Option 1

☐ Subcutaneous **Loading Dose:** 600 mg (**two 300-mg** injections)
One carton with two single-dose 300 mg/2 mL prefilled syringes (NDC: 0597-7705-72)

Ship to: ☐ HCP ☐ Patient ☐ Other _____

Instructions:
Administer a subcutaneous loading dose of 600 mg (two 300-mg injections) followed by 300 mg (one 300-mg injection) subcutaneously every 4 weeks thereafter.

☐ Subcutaneous **Ongoing Dose:** 300 mg (**one 300-mg** injection)
One carton containing one single-dose 300 mg/2 mL prefilled syringe (NDC 0597-7705-41)

Ship to: ☐ HCP ☐ Patient ☐ Other _____ ☐ 1 Refill

Instructions:
Administer 300 mg (one 300-mg injection) subcutaneously every 4 weeks.

Option 2

☐ Subcutaneous **Loading Dose:** 600 mg (**four 150-mg** injections)
Two cartons with two single-dose 150 mg/mL pre-filled syringes (NDC: 0597-0620-20)

Ship to: ☐ HCP ☐ Other _____

Instructions:
Administer a subcutaneous loading dose of 600 mg (four 150-mg injections), followed by 300 mg (two 150-mg injections) subcutaneously every 4 weeks thereafter.

☐ Subcutaneous **Ongoing Dose:** 300 mg (**two 150-mg** injections)
One carton with two single-dose 150 mg/mL pre-filled syringes (NDC: 0597-0620-20)

Ship to: ☐ HCP ☐ Patient ☐ Other _____ ☐ 1 Refill

Instructions:
Administer 300 mg (two 150-mg injections) subcutaneously every 4 weeks.

Prescriber Certification: I certify the above therapy is medically necessary and this information is complete and accurate to the best of my knowledge. I certify I am the physician who has prescribed **SPEVIGO for subcutaneous use** to the previously identified patient for an FDA-approved indication. I have reviewed the current full Prescribing Information for SPEVIGO. I authorize the SPEVIGO Patient Support Program to forward this prescription to the pharmacy dispensing SPEVIGO to the above identified patient under the SPEVIGO Bridge Program. I authorize for my patient 1 or more months of temporary shipments of SPEVIGO during a coverage delay or pending an appeal for coverage for SPEVIGO for the above identified patient. I agree to assist in efforts to secure access to SPEVIGO for my patient. I will dispense or administer Product solely to the eligible patient for whom such Product was requested. I will not attempt to seek reimbursement for any free product provided under the SPEVIGO Patient Support Program and I will not sell, trade, or distribute for sale any free product provided. I further understand that any free product provided is not contingent on any purchase obligations. I acknowledge that this program is exclusively for the purposes of patient care and not for remuneration of any sort. I further understand that any free product provided is not contingent on any purchase obligations. I understand that LEO Pharma may revise, change, or terminate the Program at any time without notice. I certify that I have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to LEO Pharma and its Partners for purposes relating to LEO Pharma patient support programs, including assisting the patient with benefits verification, prior authorization/appeals assistance, financial assistance resources and information, such as copay support or free drug programs, for which the patient may be eligible, and other support for SPEVIGO.

SIGN HERE _____ ___/___/_____
Prescriber Signature (Dispense as Written) No Stamps — Date

My signature above affirms that I have read, understand and agree to the Prescriber Certification and the Terms and Conditions of the SPEVIGO Bridge Program (See Section 10).
ATTENTION: Please follow your state's specific prescription requirements (if applicable).

Patient/Legal Guardian Certification: By signing below, I acknowledge that I have read, understand, and agree to the SPEVIGO Bridge Program Terms and Conditions. I acknowledge that I will not submit any claim for payment or reimbursement for any free product provided under the SPEVIGO Patient Support Program to my health insurance plan. For Medicare Part D Recipients: I acknowledge that this prescription is being offered outside of my prescription drug benefit and cannot be submitted for reimbursement or count towards my True Out of Pocket Cost (TrOOP).

SIGN HERE _____ ___/___/_____
Patient/Legal Guardian Signature — Date

My signature above affirms that I have read, understand and agree to the Terms and Conditions of the SPEVIGO Bridge Program (See Section 10).

8 Patient Consent: SPEVIGO Patient Assistance Program (PAP)

This section applies only to patients who are requesting financial assistance from the SPEVIGO Patient Assistance Program.

I agree this is written authorization for LEO Pharma and its vendors under Fair Credit Reporting Act (FCRA), to obtain information from my credit profile or other information from the vendor, solely for the purpose of determining financial qualifications for PAP administered by LEO Pharma. I understand that I must affirmatively agree to these terms to proceed with the financial screening process which is a condition of participation in PAP.

SIGN HERE _____ ___/___/_____
Patient/Legal Guardian Signature — Date

My signature above affirms that I have read, understand and agree to the Terms and Conditions of the SPEVIGO Patient Assistance Program.

For more information about the SPEVIGO PAP Terms and Conditions, call **833-SPEVIGO (833-773-8446)** Monday-Friday 8:00 AM - 8:00 PM ET.

Scan or click to view the SPEVIGO PAP Terms and Conditions.

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide and Instruction for use.

9 Patient Authorization: Use of Patient Information

PLEASE READ THE FOLLOWING CAREFULLY, AND THEN SIGN AND DATE WHERE INDICATED ON SECTION 1.

I hereby authorize my healthcare providers, pharmacies, and health insurers, and their service providers (collectively, "Authorized Parties") to use, release, share, or disclose information relating to my insurance benefits, medical condition, treatment, and prescription details related to my therapy ("Personal Information") to LEO Pharma and its Partners, including patient support program service providers (collectively, "LEO Pharma"), in order to receive or be eligible to receive the following LEO Pharma services (the "Services"):

- Assistance coordinating insurance coverage for, access to, or receipt of my prescription medication from LEO Pharma
- Communications through phone, text, or email about possible access, savings and support services, including, for example, LEO Pharma patient support programs, and, if I am enrolled, assistance administering my participation in those programs
- Communications through phone, text, or email about my prescription medication from LEO Pharma and treatment, including, for example, reminders, health and lifestyle tips, product, and program-related information. Communications may be customized based on Personal Information obtained from my Authorized Parties
- Participation in quality assurance activities such as surveys and feedback related to the Services or my treatment

In delivering the Services, LEO Pharma may release or disclose my Personal Information (including the personal health information set forth therein) to my Authorized Parties and certain financial assistance programs that may assist with my prescription medication payments. I understand and acknowledge LEO Pharma and Authorized Parties may combine my records and information with information and data collected from other sources and use that aggregated information to administer the Services listed above. I understand and acknowledge LEO Pharma may be required to share my records and information with law enforcement authorities or other government officials, or when required by law, statute, regulation, or a judicial or administrative order.

Once I authorize the release of my records and information, I understand and acknowledge it may be re-disclosed by the recipient, and it may no longer be protected by federal or state health privacy laws or other applicable data protection laws or regulations.

I understand that this Authorization is voluntary and that I do not have to sign it in order to get treatment or payment of eligibility in or enrollment benefits from my insurers.

I understand that I can revoke this Authorization at any time by calling **833-SPEVIGO** or by emailing Program@SpevigoPatientSupport.com or writing to:

SPEVIGO Patient Support Program
PO Box 1587
Jeffersonville, IN 47131

OR

LEO Pharma Support Services
7 Giralda Farms
Madison, NJ 07940

This Authorization will expire 5 years after I sign it, or earlier if required by law, unless I revoke it sooner. If the Authorization expires or is revoked, I understand and acknowledge that I may no longer qualify for Services from LEO Pharma, but it will not impact my treatment or my insurance benefits from Authorized Parties. I also understand and acknowledge that if an Authorized Party is disclosing my records and personal health information to LEO Pharma on an authorized, ongoing basis, my revocation of this Authorization will be effective with respect to that Authorized Party as soon as that Authorized Party receives notice of my revocation and such revocation will not affect prior uses or disclosures of my records and personal health information. I understand that I will be able to keep a copy of this Authorization and may, at any time, request a copy of this Authorization. My information may be de-identified and aggregated by LEO Pharma. I understand that my information will be used by LEO Pharma in accordance with the LEO Pharma privacy policy, located at Leo-pharma.us/privacy-policy.

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide and Instruction for use.

10 Terms and Conditions

Spevigo® (spesolimab-sbzo) Copay Program Terms and Conditions

Patients who meet the eligibility criteria may pay as little as $0; per prescription savings may vary. Restrictions, including annual benefit maximums, may apply. If you have questions about such restrictions, please call 1-833-773-8446. Benefits reset each calendar year. Benefit design may differ based on intravenous and/or subcutaneous use. Claims must be submitted within 180 days of service or dispense date. In Massachusetts and California, the validity of the SPEVIGO Copay Program and its use are subject to state law. Other state restrictions may apply. One enrollment per patient, not transferable, and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer. The SPEVIGO Copay Program is not accepted in Veterans Affairs pharmacies. Only valid for commercially insured patients in the 50 United States, territories, DC, and Puerto Rico whose insurance policy provides coverage for SPEVIGO injection, for intravenous use or subcutaneous use who are not reimbursed for the entire cost of the prescription. Offer not valid for patients without commercial coverage or patients whose prescriptions for SPEVIGO are eligible to be reimbursed, in whole or in part, by any federal healthcare programs such as Medicaid, Medicare, Medigap, the Retiree Drug Subsidy Program, VA, DOD, TRICARE, or any state patient or pharmaceutical assistance program and where prohibited by law. Offer not valid for prescriptions for SPEVIGO that are eligible to be reimbursed, in whole or in part, by any state employee health plans where prohibited by law. Patients who are members of insurance plans that claim to reduce or eliminate their patients' out of pocket co-pay, co-insurance, or deductible obligations for certain prescription drugs based upon the availability of, or patient's enrollment in, manufacturer sponsored co-pay assistance for such drugs (often termed "maximizer" programs) will have an annual maximum program benefit. If you believe your commercial insurance plan may have such limitations and need further explanation, please call 1-833-773-8446. Claims submitted utilizing the SPEVIGO Copay Program are subject to audit or validation. Offer may change at any time, without notice. This offer is intended to comply with all applicable laws and regulations, including, without limitation, the federal Anti Kickback Statute, its implementing regulations, and related guidance interpreting the federal Anti Kickback Statute.

The selling, purchasing, trading, or counterfeiting of the offer is prohibited by law. The offer has no cash value.

SPEVIGO Bridge Program Terms and Conditions

Program applies to SPEVIGO (spesolimab-sbzo) injection for subcutaneous use only ("Product"); it does not apply to SPEVIGO (spesolimab-sbzo) injection for intravenous use. Patients must be 12 years of age or older with a valid prescription for an FDA-approved use of the Product. Patients must be a resident of the United States or Puerto Rico. Patients must be enrolled in the SPEVIGO Patient Support Program with a valid Patient Authorization. The patient must have insurance that covers specialty medications; uninsured or cash-paying patients are not eligible. The patient must experience one of the following: 1) a documented delay of seven (7) calendar days or more in securing insurance coverage determination at the submission of the Prior Authorization or due to the patient switching insurance plans (i.e. the actual submission of a prior authorization, etc.); 2) a documented denial of insurance coverage or due to the patient switching insurance plans that is based on a prior authorization request for which an appeal of the coverage denial, on behalf of the patient, has been submitted or will be submitted within thirty (30) days of such denial; or 3) a documented lapse of coverage due to insurance plan changes for which an appeal or other procedural effort to regain coverage is pending. The Program does not constitute insurance. The provision of Product through the Program does not constitute any guarantee of coverage under any insurance plan or program. For each eligible patient, the Program provides Product, without charge, on a monthly basis for up to a two (2) month supply or until the patient receives insurance coverage approval. Exceptions may occur on a case-by-case basis. After eligibility is confirmed, the Program may ship a supply of the Product, in amounts to be determined in the sole discretion of the SPEVIGO Patient Support Program, to the HCP office or if specifically requested by the HCP office the Program may ship Product directly to the patient. By submitting a request for Product under the Program or by participating in the Program, the healthcare provider acknowledges and agrees that he or she: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any third-party plan or program, including any commercial or government insurance plan; (2) will advise the patient that he or she may not submit a claim to any third-party plan or program but should report his or her receipt on the Product to the patient's insurer if required by his or her plan; (3) will dispense or administer Product solely to the eligible patient for whom such Product was requested; and (4) will not sell, transfer, or otherwise dispense product to any other third party. By submitting a request for Product under the Program or by participating in the Program, the patient acknowledges and agrees that he or she: (1) will not submit any claim or other request for payment or reimbursement for Product provided under the Program to the patient or any third-party plan or program, including any commercial or government insurance plan; (2) will not submit any claim for Product to count towards his or her True Out-of-Pocket (TrOOP) costs for Medicare Part D beneficiaries (3) will report his or her receipt of Product to his or her insurer if required by his or her plan; and (4) will not sell, transfer, or otherwise dispense Product to any other third party. Patients and/or their healthcare provider must submit complete information and/or documentation required under the Program and attest to the truthfulness and accuracy of the information and/or documentation. By submitting a request for Product under the Program or by participating in the Program, the patient and healthcare provider acknowledges, understands, and agrees to the benefit, eligibility, and other program limitations. The availability of Product under the Program is not conditional on any past, present, or future purchase, including any future refills of the Product. Offer void where prohibited by law, taxed, or restricted. LEO Pharma has sole discretion to determine Program eligibility. LEO Pharma may amend, modify, or terminate Program benefits, length, and eligibility criteria at any time and without notice.

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide and Instruction for use.

What is SPEVIGO?

SPEVIGO is a prescription medicine used to treat generalized pustular psoriasis (GPP) in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg). It is not known if SPEVIGO is safe and effective in children under 12 years of age or who weigh less than 88 pounds (40 kg).

Important Safety Information

Do not receive SPEVIGO if you or your child have had a severe or life-threatening allergic reaction to spesolimab-sbzo or any of the ingredients in SPEVIGO.

What is the most important information I should know about SPEVIGO?

SPEVIGO may cause serious side effects, including:

- **Infections.** SPEVIGO may lower the ability of your or your child's immune system to fight infections and may increase your or your child's risk of infections. Your healthcare provider should check you or your child for infections and tuberculosis (TB) before starting treatment with SPEVIGO and may treat you or your child for TB before you begin treatment with SPEVIGO if you have a history of TB or have active TB. Your healthcare provider should watch you or your child closely for signs and symptoms of TB during or after treatment with SPEVIGO. Tell your healthcare provider right away if you or your child have an infection or have symptoms of an infection during or after treatment with SPEVIGO, including:
  - fevers, chills, or sweats
  - muscle aches
  - cough
  - shortness of breath
  - blood in your phlegm (mucus)
  - burning when you urinate
  - urinating more often than normal
- **Allergic reactions and infusion-related reactions.** Serious allergic reactions may happen during or after your or your child's SPEVIGO injection. If you or your child have a serious allergic reaction, your healthcare provider will stop treatment with SPEVIGO. If you or your child are given SPEVIGO in a vein (intravenously) and have an infusion-related reaction, your healthcare provider will stop your or your child's SPEVIGO infusion and treat your or your child's symptoms and may restart SPEVIGO at a slower infusion rate. Tell your healthcare provider or get emergency medical help right away if you or your child get any of the following symptoms during or after your or your child's SPEVIGO injection:
  - feeling faint, dizzy, or lightheaded
  - swelling of your face, eyelids, lips, mouth, tongue, or throat
  - trouble breathing or throat tightness
  - fever
  - mouth sores
  - chest tightness
  - hives or skin rash that is different than the rash from generalized pustular psoriasis (GPP)
  - itching
  - swollen lymph nodes

Before you or your child receive SPEVIGO, tell your healthcare provider about all of your medical conditions, including if you or your child:

- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You or your child should not receive live vaccines during and for at least 16 weeks after treatment with SPEVIGO. You or your child should be brought up to date with all vaccines before starting SPEVIGO.
- are pregnant or plan to become pregnant. It is not known if SPEVIGO can harm your or your child's unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SPEVIGO passes into your breast milk. Talk to your healthcare provider about the best way to feed your or your child's baby during treatment with SPEVIGO.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of SPEVIGO?

The most common side effects of SPEVIGO given in a vein (intravenously) for GPP flare treatment include:

- feeling tired or weak
- headache
- nausea
- itching or itchy bumps
- a collection of blood under the skin at the infusion site or bruising
- urinary tract infection.

The most common side effects of SPEVIGO when given under the skin (subcutaneously) for treatment of GPP when not experiencing a flare include:

- redness, pain, swelling, hardening, hives, or warmth at the injection site
- joint pain
- urinary tract infection
- itching

These are not all of the possible side effects of SPEVIGO. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Please see accompanying Prescribing Information, Medication Guide and Instruction for use.

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