

MEDICATION GUIDE
SPEVIGO® (spea VEE go)
(spesolimab-sbzo)
injection, for intravenous use

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 immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with SPEVIGO and may treat you 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 closely for signs and symptoms of TB after treatment with SPEVIGO. Tell your healthcare provider right away if you have an infection or have symptoms of an infection, 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 infusion of SPEVIGO. If you have a serious allergic reaction, your healthcare provider will stop treatment with SPEVIGO. If you have an infusion-related reaction, your healthcare provider will stop your SPEVIGO infusion and treat your symptoms and may restart SPEVIGO at a slower infusion rate. Tell your healthcare provider or get emergency medical help right away if you get any of the following symptoms during or after your infusion of SPEVIGO:
 - 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

See “**What are the possible side effects of SPEVIGO?**” for more information about side effects.

What is SPEVIGO?

SPEVIGO is a prescription medicine used to treat generalized pustular psoriasis (GPP) flares in adults. It is not known if SPEVIGO is safe and effective in children.

Do not receive SPEVIGO if you have had a severe or life-threatening allergic reaction to spesolimab-sbzo or any of the ingredients in SPEVIGO. See the end of this Medication Guide for a complete list of ingredients in SPEVIGO.

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

- have an infection that does not go away or that keeps coming back. See “**What is the most important information I should know about SPEVIGO?**”
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should not receive live vaccines after treatment with SPEVIGO.
- are pregnant or plan to become pregnant. It is not known if SPEVIGO can harm your 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 baby during treatment with SPEVIGO.

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

How will I receive SPEVIGO?

- Your healthcare provider will give you SPEVIGO through a needle placed in your vein (intravenous infusion) over 90 minutes.

- SPEVIGO is usually given one time. If GPP flare symptoms continue, your healthcare provider will decide if you should receive an additional treatment with SPEVIGO after 1 week.

What are the possible side effects of SPEVIGO?

SPEVIGO may cause serious side effects. See "What is the most important information I should know about SPEVIGO?"

The most common side effects of SPEVIGO include:

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

These are not all of the possible side effects of SPEVIGO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of SPEVIGO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about SPEVIGO that is written for health professionals.

What are the ingredients in SPEVIGO?

Active ingredient: spesolimab-sbzo

Inactive ingredients: arginine hydrochloride, glacial acetic acid, polysorbate 20, sodium acetate, sucrose, and Water for Injection, USP

Manufactured by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA

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For more information about SPEVIGO, including current prescribing information and Medication Guide, go to www.SPEVIGO.com, scan the code below, or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.



This Medication Guide has been approved by the U.S. Food and Drug Administration.

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