

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given Spevigo?

Spevigo contains the active ingredient spesolimab. Spevigo is used to treat flares in adult patients with generalised pustular psoriasis.

For more information, see Section [1. Why am I being given Spevigo?](#) in the full CMI.

2. What should I know before I am given Spevigo?

You should not be given Spevigo if you have ever had an allergic reaction to Spevigo or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Spevigo?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Spevigo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Spevigo?

Your doctor will administer Spevigo treatment for you using an intravenous infusion.

More instructions can be found in Section [4. How do I use Spevigo?](#) in the full CMI.

5. What should I know whilst being given Spevigo?

Things you should do	<p>Call your doctor right away if you develop signs and symptoms of:</p> <ul style="list-style-type: none">• A serious infection, such as high fever; chills; sweating; weakness; a rapid heart rate.• Signs of problems with your nervous system, such as numbness, tingling throughout your body, arm or leg weakness, or double or blurred vision• A serious allergic reaction, such as fever; a wide-spread skin rash; swollen glands; swollen face, lips or tongue; yellow skin; abdominal pain; confusion or drowsiness; nausea or vomiting; difficulty in breathing; feeling very tired or unwell. <p>Remind any doctor, dentist or pharmacist you visit that you are using Spevigo.</p>
Driving or using machines	<ul style="list-style-type: none">• Spevigo is not expected to have any effect on your ability to drive or use machines

For more information, see Section [5. What should I know whilst being given Spevigo?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: urinary tract infection; upper respiratory tract infection; itching; injection site reactions; fatigue.

Serious side effects include: serious infection; nervous system problems; allergic reactions.

For more information, including common side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Spevigo[®]

Active ingredient: spesolimab

Consumer Medicine Information (CMI)

This leaflet provides important information about being given Spevigo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Spevigo.**

Where to find information in this leaflet:

1. [Why am I being given Spevigo?](#)
2. [What should I know before I am given Spevigo?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Spevigo?](#)
5. [What should I know whilst being given Spevigo?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Spevigo?

Spevigo contains the active ingredient spesolimab. Spesolimab is an interleukin inhibitor. It works by blocking a group of proteins called interleukin 36 receptors (IL-36R) to help suppress inflammatory processes in the body.

Spevigo is used to treat flares in adult patients with generalised pustular psoriasis.

Generalised pustular psoriasis is a rare and serious condition that causes severe inflammation and scarring.

In generalised pustular psoriasis, the immune system does not work properly and triggers recurrent, severe episodes of inflammation where the skin becomes red, and painful and pus-filled blisters (pustules) appear all over the body. Inflammation of the organs and other tissues can also occur, causing fatigue, fever, body pains, muscle weakness, dehydration, and nausea.

By blocking IL-36R, Spevigo improves skin clearance, relieves pain and itching, and other symptoms of a flare in patients with generalised pustular psoriasis.

2. What should I know before I am given Spevigo?

Warnings

You should not be given Spevigo if:

- you are allergic to spesolimab, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have an infection or a history of recurrent or chronic infections
- Have tuberculosis or a history of tuberculosis
- Have received a live viral or bacterial vaccine within four weeks before treatment with Spevigo
- Intend to have a live viral or bacterial vaccine within 16 weeks after treatment with Spevigo

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

Your doctor will discuss with you the benefits and risks of being given Spevigo during pregnancy and breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Live vaccines must not be given together with Spevigo.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Spevigo.

4. How do I use Spevigo?

You doctor will administer your Spevigo treatment for you. Spevigo treatment is given using an intravenous infusion (also known as a drip). The process usually takes 90 to 180 minutes.

How much will be given

The recommended dose of Spevigo is 900 mg, given as two vials containing 450 mg/7.5mL each.

If the flare persists, your doctor may give an additional dose of 900 mg one week after the first treatment.

When you will be given Spevigo

Your doctor will discuss with you about when Spevigo treatment should be given to you.

5. What should I know whilst being given Spevigo?

Things you should do

Call your doctor straight away if you develop:

- Signs and symptoms of a **serious infection**, such as a high fever, chills, weakness, sweating, or a rapid heart rate.
- Signs of **problems with your nervous system**, such as numbness, tingling throughout your body, arm, or leg weakness, or double or blurred vision
- Signs of a **serious allergic reaction**, such as fever, wide-spread skin rash with blisters and skin loss, swollen glands/face/lips/tongue, yellowing of the skin, abdominal pain, confusion, drowsiness, nausea, vomiting, difficulty breathing, or feeling very tired

In very rare instances, intravenous infusions can cause a very serious type of delayed allergic reaction which can occur days or weeks after treatment.

Remind any doctor, dentist or pharmacist you visit that you are being given Spevigo.

Driving or using machines

Spevigo has little to no effect on the ability to drive and use machines.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Urinary tract infection <ul style="list-style-type: none"> • Burning sensation when urinating • Frequent and urgent need to urinate but only passing small amounts of urine • Cloudy, smelly, or bloody urine • Pain or pressure in the lower abdomen Upper respiratory tract infection <ul style="list-style-type: none"> • Cough with or without phlegm • Congested or runny nose • Sore throat • Headache • Breathlessness, tight chest, or wheezing • Fever Skin <ul style="list-style-type: none"> • Pruritis (itching) 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Injection site reactions, such as pain, swelling, redness, warmth, or induration (hardening caused by inflammation) Brain and nervous system <ul style="list-style-type: none"> • Fatigue 	

Serious side effects

Serious side effects	What to do
Serious infection <ul style="list-style-type: none"> • High fever • Chills • Weakness • Sweating • Rapid heart rate Brain and nervous system <ul style="list-style-type: none"> • Numbness • Tingling throughout your body • Arm or leg weakness • Double or blurred vision Allergic reactions <ul style="list-style-type: none"> • Fever • Wide-spread skin rash with blisters and skin loss • Swollen glands/face/lips/tongue • Yellowing of the skin • Abdominal pain • Confusion • Drowsiness • Nausea • Vomiting • Difficulty breathing • Feeling very tired 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Spevigo contains

Active ingredient (main ingredient)	Spesolimab
Other ingredients (inactive ingredients)	Polysorbate 20 Sodium acetate trihydrate Sucrose Arginine hydrochloride Glacial acetic acid Water for injections

You must not be given this medicine if you are allergic to any of these ingredients.

Spevigo contains 772 mg sucrose in each 900 mg/15 mL infusion.

What Spevigo looks like

Spevigo is a colourless to slightly brown-yellow, clear to slightly opalescent solution (AUST R 388597).

Who distributes Spevigo

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

78 Waterloo Road

North Ryde NSW 2113

www.boehringer-ingelheim.com.au

This leaflet was prepared in November 2023.