Package leaflet: Information for the patient

Spevigo® 450 mg concentrate for solution for infusion

spesolimab

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully, because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Spevigo is and what it is used for
2. What you need to know before you are given Spevigo
3. How Spevigo will be given
4. Possible side effects
5. How to store Spevigo
6. Contents of the pack and other information

1. What Spevigo is and what it is used for

What Spevigo is
Spevigo contains the active substance spesolimab. Spesolimab belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by blocking the activity of a protein called IL36R, which is involved in inflammation.

What Spevigo is used for
Spevigo is used alone in adults and adolescents from 12 years of age to treat flares of a rare inflammatory skin disease called generalised pustular psoriasis (GPP). During a flare, patients may experience painful skin blisters that develop suddenly over large areas of the skin. These blisters, also called pustules, are filled with pus. The skin may become red, itchy, dry, cracked or scaly. Patients may also experience more general signs and symptoms, such as fever, headache, extreme tiredness, or a burning sensation of the skin. Spevigo improves skin clearance and reduces symptoms of GPP during a flare.

2. What you need to know before you are given Spevigo

A doctor experienced in treating patients with inflammatory skin diseases will start and supervise your treatment.

You must not receive Spevigo if you:
- are allergic to spesolimab or any of the other ingredients of this medicine (listed in section 6).
- have active tuberculosis or other severe infections (see “Warnings and precautions”).

Warnings and precautions
Talk to your doctor or nurse before you are given Spevigo if you:
- currently have an infection or have an infection that keeps coming back. Fever, flu-like symptoms, tiredness or shortness of breath, a cough which will not go away, warm, red and painful skin, or a painful rash with blisters can be signs and symptoms of an infection.
- have, have had tuberculosis, or have been in close contact with someone with tuberculosis.
- have recently had a vaccination or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) for at least 16 weeks after being given Spevigo.
- experience symptoms like weakness in your arms or legs that was not there before or numbness (loss of sensation), tingling or a burning sensation in any part of your body. These might be signs of peripheral neuropathy (damage of the peripheral nerves).

Infections
Tell your doctor as soon as possible if you notice any signs or symptoms of an infection after you have been given Spevigo, see section 4 “Possible side effects”.

Allergic reactions
Seek medical help immediately if you notice any signs or symptoms of an allergic reaction while or after you are given this medicine. You can also have allergic reactions some days or weeks after receiving Spevigo. For signs and symptoms see section 4 “Possible side effects”.

Children and adolescents
Spevigo is not recommended for children under 12 years of age because it has not been studied in this age group.

Other medicines and Spevigo
Tell your doctor if you are:
- taking, have recently taken or might take any other medicines, including any other medicines to treat GPP.
- going to have or have recently had a vaccination. You should not be given certain types of vaccines (live vaccines) for at least 16 weeks after receiving Spevigo.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. This is because it is not known how this medicine will affect the baby.

It is therefore preferable to avoid the use of Spevigo during pregnancy.
If you are pregnant, you should only receive this medicine if your doctor has clearly recommended it.

Breast-feeding
It is not known whether Spevigo passes into breast milk. Spevigo may pass into breast milk in the first days after birth. You should therefore tell your doctor if you are breast-feeding or plan to breast-feed, so you and your doctor can decide if you can be given Spevigo.

Driving and using machines
Spevigo is not expected to affect your ability to drive and use machines.

Spevigo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium free’.

3. How Spevigo will be given

The recommended dose for adults and adolescents from 12 years of age and weighing at least 40 kg is 900 mg (two vials of 450 mg).

The recommended dose for adolescents from 12 years of age weighing 30 to less than 40 kg is 450 mg (one vial of 450 mg).

Your doctor or nurse will give you this medicine by infusion (drip) into a vein. It will be given over a period of 90 minutes, up to a maximum of 180 minutes if the infusion is slowed down or stopped temporarily.

If you still experience flare symptoms your doctor can decide to give you a second dose of Spevigo one week after the first.

If you have any further questions on the use of this medicine, ask your doctor.

If you are given more Spevigo than you should
This medicine will be given to you by your doctor or nurse. If you think you have been given too much Spevigo, tell your doctor or nurse straight away.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek medical help immediately if you notice any signs or symptoms of an allergic reaction while or after you are given this medicine. These may include:
- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps, that is different from your GPP symptoms
- feeling faint.

You can also have allergic reactions some days or weeks after receiving Spevigo.
Seek medical help immediately if you develop any widespread skin rash that was not there before, fever, and/or facial swelling 2-8 weeks after receiving the medicine. These might be signs of a delayed allergic reaction (hypersensitivity).

Tell your doctor as soon as possible if you notice any signs or symptoms of an infection.
Very common (may affect more than 1 in 10 people).
These may include:
- fever, cough
- frequent urination, pain or burning while urinating or bloody urine, which may be symptoms of urinary tract infections

Tell your doctor or nurse if you get any of the following other side effects:

Very common (may affect more than 1 in 10 people)
- redness, swelling, hardening, warmth, pain, peeling of the skin, small, solid raised bumps on the skin, itching, skin rash, or hives at the injection site

Common (may affect up to 1 in 10 people)
- itching
- feeling tired

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Spevigo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C) (see information for Healthcare Professionals at the end of this Package leaflet).

Do not freeze.

Store in the original package in order to protect from light.

6. Contents of the pack and other information

What Spevigo contains

- The active substance is spesolimab. Each vial contains 450 mg spesolimab in 7.5 mL of concentrate for solution for infusion.
- The other ingredients are sodium acetate trihydrate (E262), glacial acetic acid (E260) (for pH adjustment), sucrose, arginine hydrochloride, polysorbate 20 (E432) and water for injections.

What Spevigo looks like and contents of the pack

Spevigo concentrate for solution for infusion is a clear to slightly opalescent, colourless to slightly brownish-yellow solution supplied in a 10 mL colourless glass vial (type I glass), with a coated rubber stopper and aluminium crimp cap with blue plastic button.

Each pack contains two vials.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in 11/2024.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine.

The MHRA will review new information on this medicine at least every year and this leaflet will be updated as necessary.

The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Posology and method of administration

The recommended dose for adults and adolescents from 12 years of age and weighing at least 40 kg is a single dose of 900 mg (2 vials of 450 mg) administered as an intravenous infusion. If flare symptoms persist, an additional 900 mg dose may be administered 1 week after the initial dose.

The recommended dose for adolescents from 12 years of age weighing ≥ 30 and < 40 kg is a single dose of 450 mg (1 vial of 450 mg) administered as an intravenous infusion. If flare symptoms persist, an additional 450 mg dose may be administered 1 week after the initial dose.

Spevigo must be diluted before use. It should not be administered as an intravenous push or bolus.

Following dilution with sodium chloride 9 mg/mL (0.9%) solution for injection, Spevigo is administered 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 minutes. No other infusion should be administered in parallel via the same intravenous access.

In the event that the infusion is slowed or temporarily stopped, the total infusion time (including stop time) should not exceed 180 minutes.

Handling instructions

- The vial should be visually inspected before use.
  - Spevigo is a colourless to slightly brownish-yellow, clear to slightly opalescent solution.
  - If the solution is cloudy, discoloured, or contains large or coloured particulates, the vial should be discarded.
- Spesolimab sterile concentrate is for single use only.
- Aseptic technique must be used to prepare the solution for infusion:
  - For the recommended dose of 900 mg, draw and discard 15 mL from a 100 mL container of sodium chloride 9 mg/mL (0.9%) solution for injection and replace slowly with 15 mL spesolimab sterile concentrate (two vials of 450 mg/7.5 mL).
  - For the recommended dose of 450 mg, draw and discard 7.5 mL from a 100 mL container of sodium chloride 9 mg/mL (0.9%) solution for injection and replace slowly with 7.5 mL spesolimab sterile concentrate (one vial of 450 mg/7.5 mL).
  - Mix gently before use. The diluted spesolimab infusion solution should be used immediately.
- Spevigo must not be mixed with other medicinal products. A pre-existing intravenous line may be used for administration of the diluted spesolimab infusion solution. The line must be flushed with sodium chloride 9 mg/mL (0.9%) solution for injection prior to and at the end of infusion. No other infusion should be administered in parallel via the same intravenous access.
- Spevigo is compatible with infusion sets composed of polyvinylchloride (PVC), polyethylene (PE), polypropylene (PP), polybutadiene and polyurethane (PUR), and in-line filter membranes composed of polyethersulfone (PES, neutral and positively charged) and positively charged polyamide (PA).

Storage conditions

Unopened vial

- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- Store in the original package in order to protect from light.
- Prior to use, the unopened vial may be kept at temperatures up to 30 °C for up to 24 hours, if stored in the original package in order to protect from light.

After opening

- From a microbiological point of view, once opened, the medicinal product should be diluted and infused immediately.

After preparation of infusion

- Chemical and physical in-use stability of the diluted solution has been demonstrated for 24 hours at 2 °C – 30 °C.
- From a microbiological point of view, the diluted solution for infusion should be used immediately. If not used immediately, in use storage conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 °C – 8 °C, unless dilution has taken place in controlled and validated aseptic conditions. For the time between preparation and start of administration the solution for infusion should be protected from light following local standard procedures.