

## Package leaflet: Information for the patient

### Spevigo® 150 mg solution for injection in pre-filled syringe 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 use Spevigo
3. How to use Spevigo
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 in adults and adolescents from 12 years of age to prevent 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 clears pustules and other skin manifestations and can therefore help to reduce the signs and symptoms of your disease.

#### 2. What you need to know before you use Spevigo

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

##### Do not use 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 and during the use of 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. Your doctor will check if you need any vaccines before you start using 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).

It is important to keep a record of the batch number of your Spevigo.

Every time you get a new pack of Spevigo, note down the date and the batch number (which is on the packaging after “Lot”) and keep this information in a safe place.

### Infections

Tell your doctor as soon as possible if you notice any signs or symptoms of an infection while you are using 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 you are using or after you have used this medicine. You can also have allergic reactions some days or weeks after starting the use of 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.
- 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.

If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of 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 using 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 use Spevigo.

### **Driving and using machines**

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

### **Spevigo contains polysorbate**

This medicine contains 0.4 mg of polysorbate 20 in each 1 mL pre-filled syringe. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

### **Spevigo contains sodium**

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

### 3. How to use Spevigo

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### How much Spevigo to use

Adults and adolescents from 12 years of age and weighing at least 40 kg

	How much?	When?
<b>1<sup>st</sup> dose</b>	600 mg ( <b>four</b> 150 mg injections)	When your doctor tells you
<b>Further doses</b>	300 mg ( <b>two</b> 150 mg injections)	Every 4 weeks starting after the 1 <sup>st</sup> dose

The first dose should be given by your doctor or nurse.

You and your doctor or nurse will decide if you should inject this medicine yourself. Do not inject yourself with this medicine unless you have been trained by your doctor or nurse. A caregiver may also give your injections after they have been trained.

**Read the ‘Instructions for use’ at the end of this leaflet before injecting Spevigo yourself.**

Adolescents from 12 years of age weighing 30 to less than 40 kg

	How much?	When?
<b>1<sup>st</sup> dose</b>	300 mg ( <b>two</b> 150 mg injections)	When your doctor tells you
<b>Further doses</b>	150 mg ( <b>one</b> 150 mg injection)	Every 4 weeks starting after the 1 <sup>st</sup> dose

**Spevigo should be given by your doctor or nurse.**

#### If you use more Spevigo than you should

If you have used more Spevigo than you should or the dose has been given sooner than prescribed, talk to your doctor.

#### If you forget to use Spevigo

If you forget to use Spevigo, inject a dose as soon as you realise. Talk to your doctor if you are not sure what to do.

#### If you stop using Spevigo

Do not stop using Spevigo without talking to your doctor first. If you stop treatment, your symptoms may come back or you may experience a flare.

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

### 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 using or after you have used 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 you have used 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 you have used 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.** These may include:

**Very common** (may affect more than 1 in 10 people)

- fever, cough

**Common** (may affect up to 1 in 10 people)

- 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

**Not known** (frequency cannot be estimated from the available data)

- allergic reaction

### **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](http://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 pre-filled syringe and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). **Do not** freeze. **Do not** use Spevigo if frozen, even if it has been thawed.

If needed, Spevigo can be stored at temperatures up to 25 °C for up to 14 days. Throw away Spevigo if it has been kept at temperatures up to 25 °C for more than 14 days.

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

**Do not** use this medicine if the liquid is cloudy or contains flakes or large or coloured particles.

**Do not** throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Spevigo contains**

- The active substance is spesolimab. Each pre-filled syringe contains 150 mg spesolimab in 1 mL solution.
- 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 solution for injection is a clear to slightly opalescent, colourless to slightly brownish-yellow solution in a pre-filled syringe with safety cover. The liquid may contain tiny white or clear particles. Each pre-filled syringe contains 150 mg in 1 mL solution for injection.

Each pack contains 2 pre-filled syringes.

### **Marketing Authorisation Holder**

LEO Pharma A/S  
Industriparken 55  
DK 2750 Ballerup  
Denmark

### **Manufacturer**

Boehringer Ingelheim Pharma GmbH & Co. KG  
Birkendorfer Strasse 65  
88397 Biberach an der Riss  
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

### **United Kingdom**

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Tel: +44 (0) 1844 347333

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## Instructions for use

### Spevigo® 150 mg solution for injection in pre-filled syringe

This “Instructions for use” contains information on how to inject Spevigo if the prescribed dose for you or your child requires **2 pre-filled syringes of Spevigo 150 mg**.

#### Getting to know Spevigo

The pre-filled syringe contains the active substance spesolimab in a solution for subcutaneous injection that helps to deliver a fixed dose of spesolimab.

Before you start using this medicine on your own or your child, first make sure that you get trained by your doctor or nurse. Then read the package leaflet and these instructions for use to make sure you get the correct dose. If you are visually impaired and cannot see well, you must be assisted by a trained caregiver.

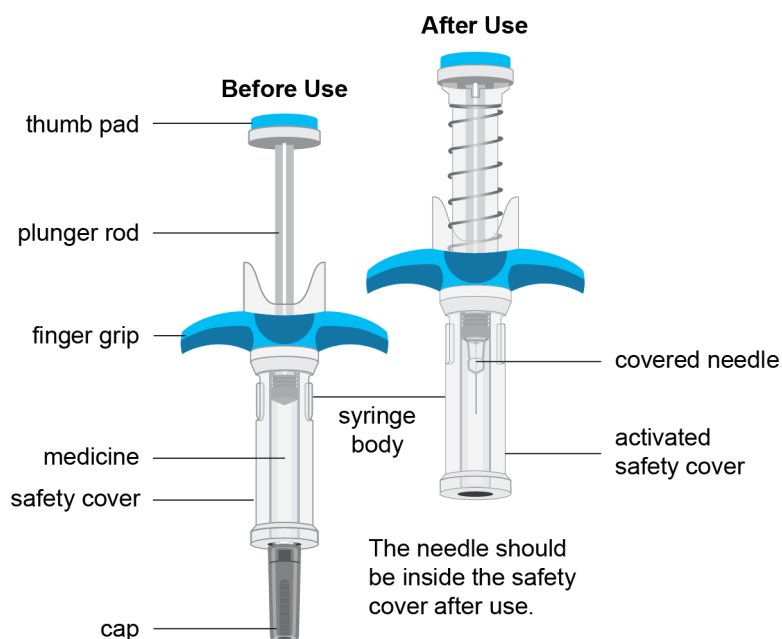
If you have further questions, ask your doctor, pharmacist or nurse.

Spevigo is for single use. **Do not** reuse the pre-filled syringe.

#### This is what Spevigo pre-filled syringe looks like

Spevigo is a pre-filled syringe with a safety cover. The needle is pulled back into the safety cover after injection.

The following picture shows Spevigo before use and after use with the activated safety cover.



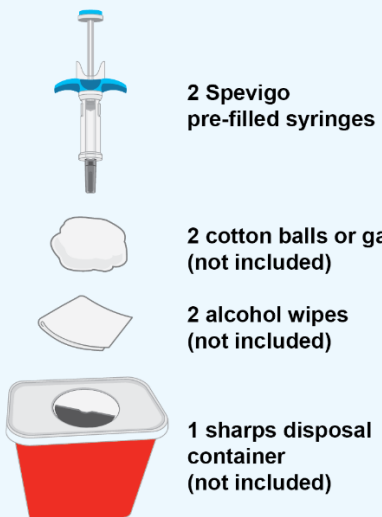


Your healthcare professional has prescribed a dose of Spevigo for you or your child that requires two injections to deliver a complete dose. You must inject the contents of both pre-filled syringes that come in the carton to deliver the complete dose.

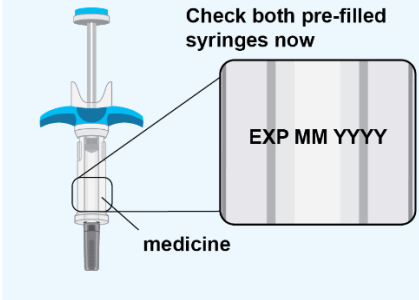
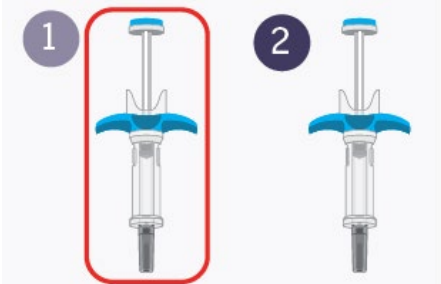
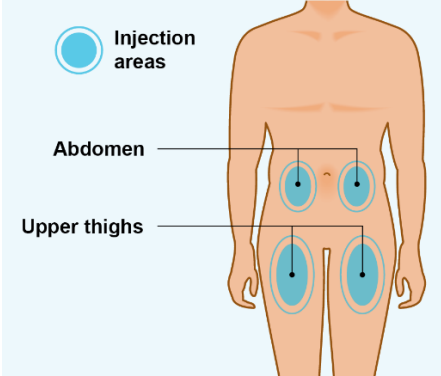

#### Important information you need to know before injecting Spevigo

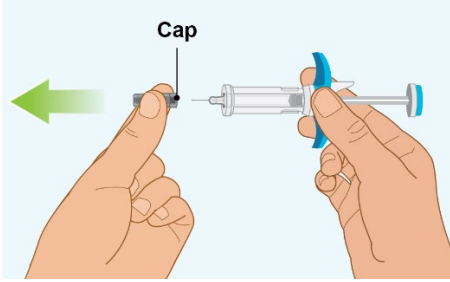
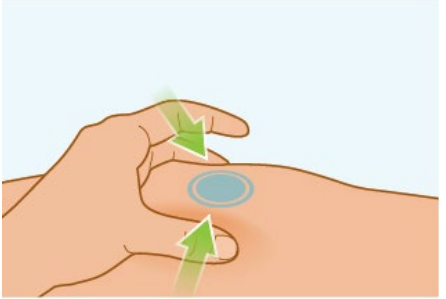
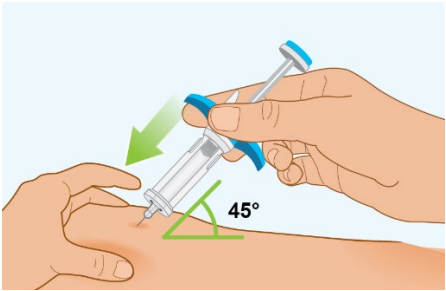
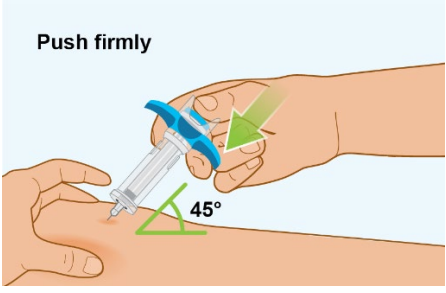
- **Do not** use the pre-filled syringe until you have been shown the right way to give the injection and have read and understood these handling instructions.


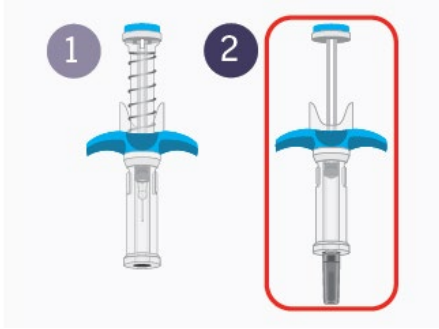

- Inspect the carton that the product comes in to be sure that you have the correct medicine, the correct number of pre-filled syringes for your or your child’s prescribed dose, for any damage, and the expiry date.
- **Do not** remove the cap until you are ready to inject.
- **Do not** use Spevigo:
  - if the liquid is cloudy or contains flakes or large particles.
  - if the **expiry date (EXP)** has passed.
  - if the pre-filled syringes have been dropped or look damaged.
- It is important to keep a record of the batch number of your Spevigo. Every time you get a new pack of Spevigo, note down the date and the batch number (which is on the packaging after “Lot”) and keep this information in a safe place.
- Inject Spevigo under the skin (subcutaneous injection) in either the upper thighs or stomach area (abdomen). **Do not** inject Spevigo into any other area of the body.
- If you have any problems with your injection, **do not** repeat the injection steps with Spevigo pre-filled syringe. Call your doctor for help.
- If you have further questions, ask your doctor or pharmacist.

Follow the steps below when you use Spevigo

<p><b>STEP 1</b></p>  <p>2 Spevigo pre-filled syringes</p> <p>2 cotton balls or gauze (not included)</p> <p>2 alcohol wipes (not included)</p> <p>1 sharps disposal container (not included)</p>	<p><b>Gathering supplies</b></p> <ul style="list-style-type: none"> <li>• Take the Spevigo carton out of the refrigerator and remove the pre-filled syringes from the carton.</li> <li>• Gather supplies listed on the left side and place them on a clean, flat work surface in a well-lit area.</li> <li>• If you do not have all the supplies listed, contact your pharmacist.</li> <li>• For disposal, see step 10: “<b>Disposing of the used pre-filled syringes and caps.</b>”</li> </ul>
<p><b>STEP 2</b></p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>Bring medicine to room temperature</p>  <p>15-30 minutes</p> </div> <div style="text-align: center;"> <p>Wash hands</p>  </div> </div>	<p><b>Preparing to inject Spevigo</b></p> <ul style="list-style-type: none"> <li>• Wait 15 to 30 minutes to allow the medicine to reach room temperature to avoid discomfort during injection. <b>Do not</b> speed up the warming process in any way, such as using the microwave or placing the syringe in warm water.</li> <li>• <b>Do not</b> leave the pre-filled syringes in direct sunlight.</li> <li>• Wash your hands well with soap and water and dry them.</li> </ul>

<p><b>STEP 3</b></p>	<p><b>Inspecting the pre-filled syringes</b></p>
	<p><b>Check both pre-filled syringes now:</b></p> <ul style="list-style-type: none"> <li>• Check to make sure the medicine name and dose on the pre-filled syringes match your or your child’s prescription.</li> <li>• Check the expiry date (EXP) on both pre-filled syringes. <b>Do not</b> use if the expiry date has passed.</li> <li>• Check both pre-filled syringes for damage, cracks, and leakage. <b>Do not</b> use if any part of the pre-filled syringes appears cracked, broken, or is leaking.</li> <li>• Make sure the medicine in both pre-filled syringes is colourless to slightly yellow. It may contain tiny white or clear particles. <b>Do not</b> use if the medicine is cloudy or has flakes or large particles in it.</li> <li>• It is normal to see air bubbles, they do not need to be removed.</li> <li>• <b>Do not</b> use if the Spevigo pre-filled syringes have been dropped.</li> </ul>
<p><b>Preparing for your first injection</b></p>	
	<p><b>Prepare for the first of two injections.</b></p> <p><b>Remember, you will repeat the following steps with the second pre-filled syringe right away after your first injection.</b></p> <p><b>Two injections are needed for a complete dose.</b></p>
<p><b>STEP 4</b></p>	<p><b>Choosing the injection site</b></p>
	<p>Choose an injection site.</p> <ul style="list-style-type: none"> <li>• You may use an area on your: <ul style="list-style-type: none"> <li>○ <b>upper thighs</b> or</li> <li>○ <b>stomach area (abdomen)</b>, except for an area 5 cm around your navel (belly button).</li> </ul> </li> <li>• <b>Choose a different injection site</b> each time you inject, at least 2 cm away from the last injection site.</li> <li>• <b>Do not</b> inject into an area near your waistline or belly button.</li> <li>• <b>Do not</b> inject into areas that are tender, bruised, red, hard, or scarred.</li> <li>• <b>Do not</b> inject through clothes.</li> </ul>
<p><b>STEP 5</b></p>	<p><b>Cleaning the injection site</b></p>
	<ul style="list-style-type: none"> <li>• Clean the injection site with an alcohol wipe and let air dry.</li> <li>• <b>Do not</b> touch this area again before injecting.</li> <li>• <b>Do not</b> fan or blow on the clean area.</li> </ul>

<p><b>STEP 6</b></p>	<p><b>Removing the cap</b></p>
	<ul style="list-style-type: none"> <li>• Hold the pre-filled syringe by the finger grip with one hand. With the other hand, pull the cap straight off. <ul style="list-style-type: none"> <li>○ <b>Do not</b> pull on or hold the plunger rod.</li> <li>○ <b>Do not</b> twist the cap. Twisting the cap could damage the needle.</li> <li>○ <b>Do not</b> use the prefilled syringe if the needle is bent or damaged. If you accidentally bend the needle, <b>do not</b> attempt to straighten it.</li> </ul> </li> <li>• Put the cap aside.</li> <li>• Use right away after removing the cap. <ul style="list-style-type: none"> <li>○ <b>Do not</b> try to recap the needle. Re-capping can lead to needle-stick injury.</li> <li>○ <b>Do not</b> touch the needle or let the needle touch anything before injecting.</li> </ul> </li> </ul>
<p><b>STEP 7</b></p>	<p><b>Pinch the skin</b></p>
	<ul style="list-style-type: none"> <li>• Gently pinch the area of cleaned skin around your injection site and hold it firmly.</li> <li>• Keep the skin pinched during the entire injection. You will inject into the pinched skin.</li> <li>• <b>Do not</b> let go until you have removed the needle from your skin at the end of the injection.</li> </ul>
<p><b>STEP 8</b></p>	<p><b>Before injecting, review steps A, B, and C to learn the correct way to inject</b></p>
<p><b>Important: Do not move the pre-filled syringe when inserting the needle into your skin, while injecting, or when removing the needle from your skin.</b></p>	
	<ul style="list-style-type: none"> <li>• Hold the pre-filled syringe by the blue finger grip. Avoid touching the blue thumb pad.</li> <li>• Using a quick, “dart-like” motion, insert the needle into the pinched skin at about a <b>45-degree angle</b>.</li> <li>• <b>Do not</b> move the needle while inserting or during the injection.</li> </ul>
<p><b>A Inserting the needle</b></p>	
 <p>Push firmly</p>	<p><b>To inject Spevigo:</b></p> <ul style="list-style-type: none"> <li>• Use your thumb to slowly press down on the blue thumb pad to push the plunger rod down inside the syringe body.</li> <li>• Continue pressing on the blue thumb pad until the plunger rod has moved all the way down.</li> <li>• Make sure that the blue thumb pad cannot be pressed any further so that <b>the built-in safety cover can be activated</b>.</li> </ul>

<p><b>B Injecting the medicine</b></p>	
	<ul style="list-style-type: none"> <li>• <b>Slowly remove your thumb</b> from the blue thumb pad, to move the needle out of your skin and up into the safety cover. <ul style="list-style-type: none"> <li>○ Check that the thumb pad springs back and that the needle is inside the safety cover.</li> <li>○ If the needle is not inside the safety cover call your doctor. You may not have received a full dose.</li> </ul> </li> <li>• If there is bleeding, press a cotton ball or gauze on the site for a few seconds.</li> <li>• <b>Do not</b> rub the injection site.</li> <li>• Apply a plaster if needed.</li> </ul>
<p><b>C Checking injection is complete</b></p>	
<p><b>STEP 9</b></p>	<p><b>Second injection</b></p>
	<ul style="list-style-type: none"> <li>• <b>Choose a different injection site.</b> The new injection site should be at least 2 cm away from last injection site.</li> <li>• <b>Take the second pre-filled syringe.</b></li> <li>• <b>Repeat steps 4 through 8 right away.</b></li> <li>• Then continue to step 10.</li> </ul> <p><b>Important:</b> You must inject the contents of both Spevigo pre-filled syringes to give a complete dose.</p>
<p><b>STEP 10</b></p>	<p><b>Disposing of the used pre-filled syringes and caps</b></p>
	<ul style="list-style-type: none"> <li>• Put the used pre-filled syringes and caps in a sharps disposal container right away after use.</li> <li>• <b>Do not</b> throw away the pre-filled syringes in the household waste.</li> <li>• Your doctor, pharmacist, or nurse will tell you how to return the full sharps disposal container.</li> <li>• <b>Do not</b> reuse the pre-filled syringes.</li> </ul> <p><b>Important:</b> Always keep the sharps disposal container out of the reach of children.</p>

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