

**INSTRUCTIONS FOR USE  
SPEVIGO® (spea VEE go)  
(spesolimab-sbzo)  
injection, for subcutaneous use  
150 mg/mL**

**Two 150 mg/mL single-dose prefilled syringes for a total of 300 mg dose**

This Instructions for Use contains information on how to inject SPEVIGO.

Read **both sides** of this Instructions for Use before you use SPEVIGO for the first time and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment. Your healthcare provider should show you or your child the right way to inject SPEVIGO before you try to inject yourself or your child for the first time. In children 12 years of age and older, SPEVIGO should be given under the supervision of an adult.

SPEVIGO is for one-time use only. **Do not** reuse the prefilled syringes.

Your healthcare provider has prescribed a dose of SPEVIGO for you or your child that requires 2 injections (2 prefilled syringes) to deliver a complete dose.

**You must inject the contents of both SPEVIGO prefilled syringes that come in the carton to deliver the complete dose.**

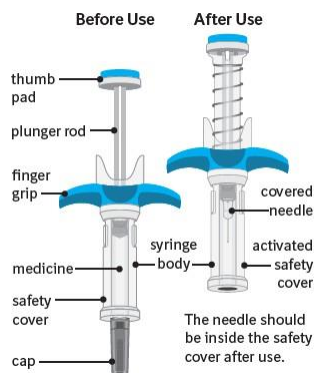


**Getting to know SPEVIGO:**

SPEVIGO comes in a prefilled syringe with a safety cover. The needle is pulled back into the safety cover after injection.

**Guide to parts:**

The figure below shows SPEVIGO before use, and after use with the activated safety cover.



**Important information you need to know before injecting SPEVIGO:**




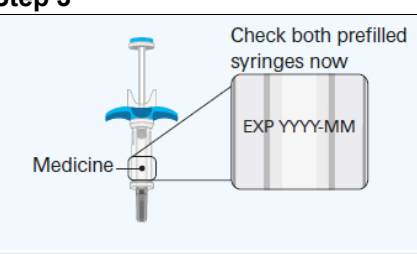
- You must inject the contents of both SPEVIGO prefilled syringes to deliver a complete dose.
- Inspect the SPEVIGO carton to be sure that you have the correct medicine, 2 prefilled syringes for your or your child's prescribed dose, for any damage, and the expiration date (EXP).
- **Do not** use SPEVIGO if the liquid is cloudy or contains flakes or large or colored particles.
- **Do not** use SPEVIGO if the **expiration date (EXP)** has passed.
- **Do not** use SPEVIGO if the prefilled syringe has been dropped.
- **Do not** remove the cap until you are ready to inject.
- 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.


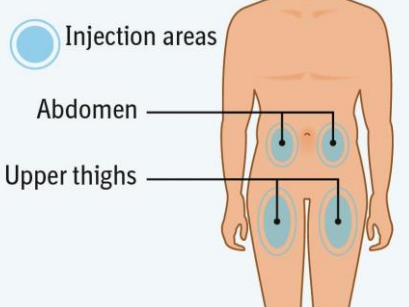



**Storing SPEVIGO:**

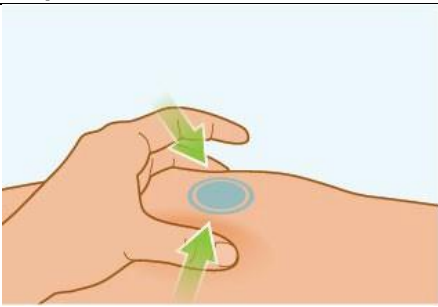
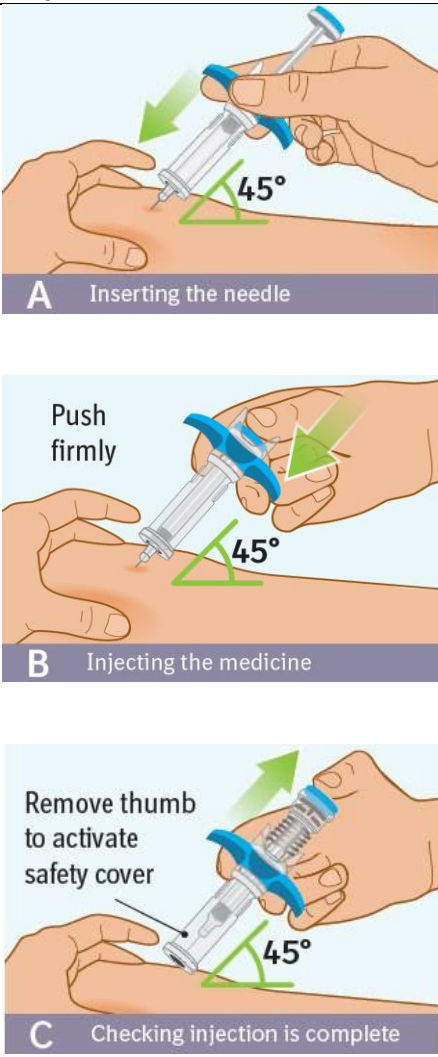
- Store SPEVIGO prefilled syringes in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze SPEVIGO. **Do not** use SPEVIGO if frozen, even if it has been thawed.
- Store SPEVIGO in the original carton until use to protect from light.

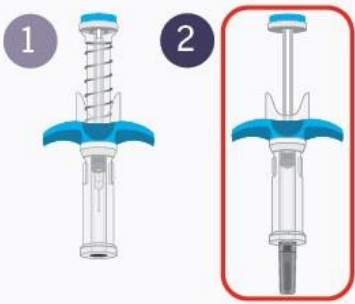



**Keep SPEVIGO and all medicines out of the reach of children.**

<p><b>Step 1</b></p>  <p>2 SPEVIGO Prefilled syringes</p> <p>2 Cotton balls or gauze (not included)</p> <p>2 Alcohol wipes (not included)</p> <p>1 Sharps container (not included)</p>	<p><b>Gather supplies</b></p> <ul style="list-style-type: none"> <li>• Take the SPEVIGO carton out of the refrigerator and remove the prefilled syringes from the carton.</li> <li>• Gather supplies listed above 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 above, contact your pharmacist.</li> </ul> <ul style="list-style-type: none"> <li>• See Step 10: <b>“Disposing of the used SPEVIGO prefilled 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 prefilled syringes in direct sunlight.</li> <li>• <b>Do not</b> remove the needle cap until you are ready to inject.</li> <li>• Wash your hands well with soap and water and dry them.</li> </ul>
<p><b>Step 3</b></p>  <p>Check both prefilled syringes now</p> <p>EXP YYYY-MM</p> <p>Medicine</p>	<p><b>Inspecting the prefilled syringes</b></p> <p><b>Check both prefilled syringes now:</b></p> <ul style="list-style-type: none"> <li>• Check to make sure the medicine name SPEVIGO and the dose on your prefilled syringes match your or your child's prescribed dose.</li> <li>• Check the expiration date (EXP) on both prefilled syringes. <b>Do not</b> use if the expiration date has passed.</li> </ul>

	<ul style="list-style-type: none"> <li>• Check both prefilled syringes for damage, cracks, and leakage. <b>Do not</b> use if any part of the prefilled syringes appear cracked, broken, or are leaking.</li> <li>• Make sure the medicine in both prefilled syringes is clear and colorless to slightly brownish-yellow. It may contain tiny white or clear particles. <b>Do not</b> use if the medicine is cloudy or has flakes or large or colored 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 prefilled syringes have been dropped.</li> </ul>
<b>Preparing for your first injection</b>	
	<p><b>Prepare for the first of 2 injections.</b></p> <p><b>You will repeat the following steps with the second syringe right away after your first injection.</b></p> <p><b>2 injections are needed for a complete dose.</b></p>
<b>Step 4</b>	
	<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 2 inches around your navel (belly button).</li> </ul> </li> <li>• Choose a <b>different injection site</b> each time you inject, at least 1 inch away from the last injection site. Alternate between upper thigh or stomach-area for each complete dose.</li> <li>• <b>Do not</b> inject 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>
<b>Step 5</b>	
	<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> 
<b>Step 6</b>	
	<p><b>Removing the cap from the prefilled syringe</b></p> <ul style="list-style-type: none"> <li>• Hold the prefilled 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>• Throw away the cap. See Step 10: <b>“Disposing of the used SPEVIGO prefilled syringes and caps.”</b></li> <li>• Proceed to the next step 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> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ <b>Do not</b> touch the needle or let the needle touch anything before injecting.</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 your injection is complete. See Step 8C: “<b>Checking injection is complete.</b>”</li> </ul>
<p><b>Step 8</b></p>  <p><b>A</b> Inserting the needle</p> <p><b>B</b> Injecting the medicine</p> <p><b>C</b> Checking injection is complete</p>	<p><b>Injecting SPEVIGO</b></p> <p><b>A. Inserting the needle:</b></p> <ul style="list-style-type: none"> <li>• Hold the prefilled 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>B. Injecting the medicine:</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>C. Checking injection is complete:</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 healthcare provider. 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 an adhesive bandage if needed.</li> </ul> <p><b>Important: Do not</b> move the prefilled syringe when inserting the needle into your skin, while injecting, or when removing the needle from your skin.</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 1 inch away from last injection site. Alternate between upper thigh or stomach-area for each complete dose.</li> <li>• <b>Get second prefilled 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> <b>You must inject the contents of both SPEVIGO prefilled syringes to give a complete dose.</b></p>
<p><b>Step 10</b></p> 	<p><b>Throwing away (disposing of) the used SPEVIGO prefilled syringes and caps</b></p> <ul style="list-style-type: none"> <li>• Put the used prefilled syringes and caps in an FDA-cleared sharps disposal container right away after use.</li> <li>• If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: <ul style="list-style-type: none"> <li>○ made of a heavy-duty plastic,</li> <li>○ can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,</li> <li>○ upright and stable during use,</li> <li>○ leak resistant, and</li> <li>○ properly labeled to warn of hazardous waste inside the container.</li> </ul> </li> </ul> <p>When your sharps disposal container is almost full, you will need to follow your sharps community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>.</p> <ul style="list-style-type: none"> <li>• <b>Do not</b> reuse the prefilled syringes.</li> <li>• <b>Do not</b> throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this.</li> <li>• <b>Do not</b> recycle your used sharps disposal container.</li> </ul> <p><b>Important:</b> Always keep the sharps disposal container out of the reach of children.</p>
<p>If you have any problems with your injection, do not use another SPEVIGO prefilled syringe. Call your healthcare provider or pharmacist for help.</p> <p><b>For more information call 1-833-SPEVIGO.</b></p>	

Manufactured by: LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Denmark  
Distributed by: LEO Pharma Inc., Madison, NJ 07940, USA  
U.S. License No. 2169

SPEVIGO® is a registered trademark of LEO Pharma A/S.  
© 2026 LEO Pharma Inc. All rights reserved.

For more information about SPEVIGO, including current prescribing information and Medication Guide, go to [www.SPEVIGO.com](http://www.SPEVIGO.com), or call LEO Pharma, Inc. at 1-833-SPEVIGO.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.  
Revised: 03/2026

**INSTRUCTIONS FOR USE**  
**SPEVIGO® (spea VEE go)**  
**(spesolimab-sbzo)**  
**injection, for subcutaneous use**  
**300 mg/2 mL**

**One 300 mg/2 mL single-dose prefilled syringe for a total of 300 mg dose**

This Instructions for Use contains information on how to inject SPEVIGO.

Read **both sides** of this Instructions for Use before you use SPEVIGO for the first time and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment. Your healthcare provider should show you or your child the right way to inject SPEVIGO before you try to inject yourself or your child for the first time. In children 12 years of age and older, SPEVIGO should be given under the supervision of an adult.

SPEVIGO is for one-time use only. **Do not** reuse the prefilled syringe.

Your healthcare provider has prescribed a dose of SPEVIGO for you or your child that requires 1 injection to deliver a complete dose.

**You must inject the contents of the SPEVIGO prefilled syringe that comes in the carton to deliver the complete dose.**

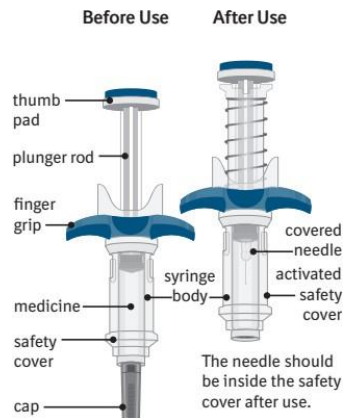


**Getting to know SPEVIGO:**

SPEVIGO comes in a prefilled syringe with a safety cover. The needle is pulled back into the safety cover after injection.

**Guide to parts:**

The figure below shows SPEVIGO before use, and after use with the activated safety cover.



## Important information you need to know before injecting SPEVIGO

- Inspect the SPEVIGO carton to be sure that you have the correct medicine, 1 prefilled syringe for your or your child's prescribed dose, for any damage, and the expiration date (EXP).
- **Do not** use SPEVIGO if the liquid is cloudy or contains flakes or large or colored particles.
- **Do not** use SPEVIGO if the **expiration date (EXP)** has passed.
- **Do not** use SPEVIGO if the prefilled syringe has been dropped.
- **Do not** remove the cap until you are ready to inject.
- 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.

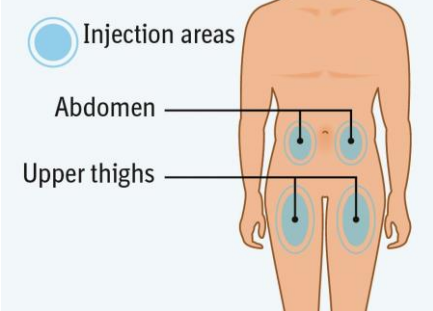
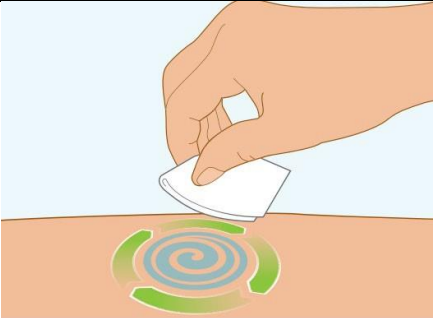
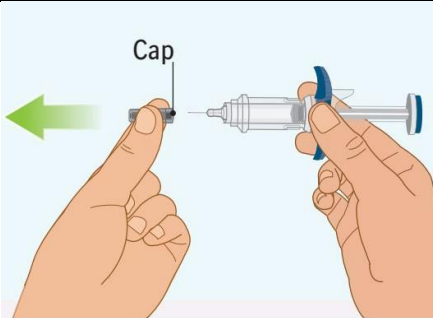
### Storing SPEVIGO:

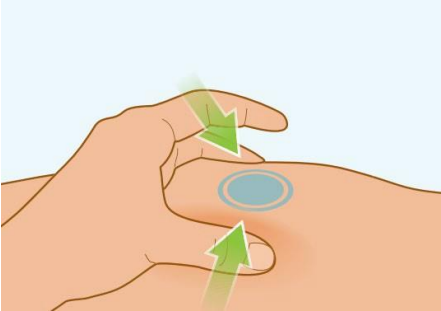
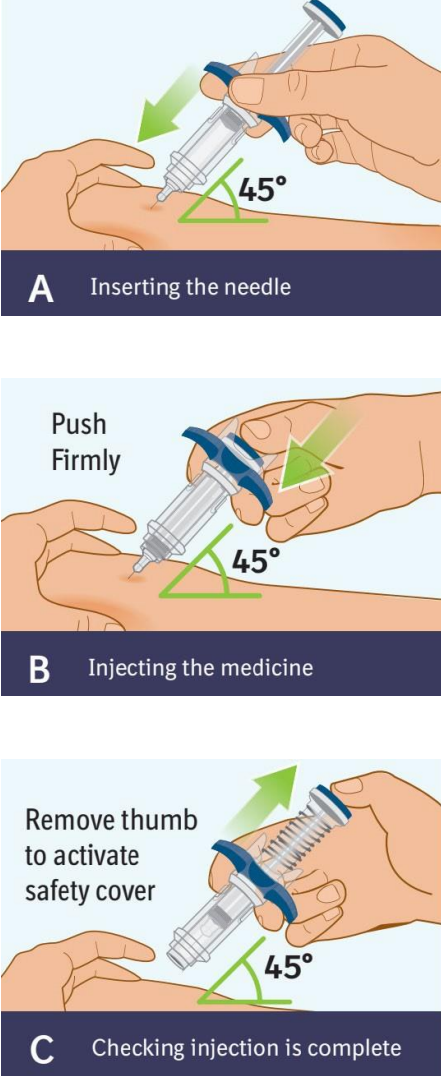
- Store SPEVIGO prefilled syringes in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze SPEVIGO. **Do not** use SPEVIGO if frozen, even if it has been thawed.
- Store SPEVIGO in the original carton until use to protect from light.
- If needed, SPEVIGO 300 mg/2 mL prefilled syringe may also be stored at room temperature up to 77°F (25°C) for up to 14 days.
- Throw away (dispose of) SPEVIGO 300 mg/2 mL prefilled syringe that has been left at room temperature for more than 14 days.

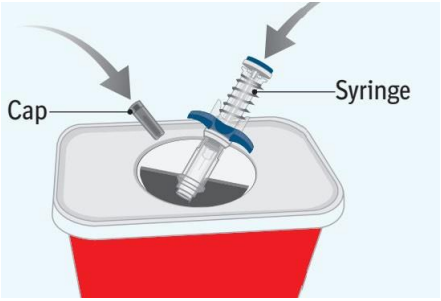


### Keep SPEVIGO and all medicines out of the reach of children.

<p><b>Step 1</b></p> <ul style="list-style-type: none"> <li>1 SPEVIGO Prefilled syringe</li> <li>1 Cotton ball or gauze (not included)</li> <li>1 Alcohol wipe (not included)</li> <li>1 Sharps container (not included)</li> </ul>	<p><b>Gather supplies</b></p> <ul style="list-style-type: none"> <li>• Take the SPEVIGO carton out of the refrigerator and remove the prefilled syringe from the carton.</li> <li>• Gather supplies listed above 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 above, contact your pharmacist.</li> <li>• See Step 9: <b>“Disposing of the used SPEVIGO prefilled syringe and cap.”</b></li> </ul>
<p><b>Step 2</b></p> <p>Bring medicine to room temperature</p> <p>15-30 minutes</p> <p>Wash hands</p>	<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.</li> <li>• <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 prefilled syringe in direct sunlight.</li> <li>• <b>Do not</b> remove the needle cap until you are ready to inject.</li> <li>• Wash your hands well with soap and water and dry them.</li> </ul>
<p><b>Step 3</b></p> <p>Check both prefilled syringes now</p> <p>EXP YYYY-MM</p> <p>Medicine</p>	<p><b>Inspecting the prefilled syringe</b></p> <p><b>Check the prefilled syringe:</b></p> <ul style="list-style-type: none"> <li>• Check to make sure the medicine name SPEVIGO and the dose on the prefilled syringe match your or your child's prescribed dose.</li> <li>• Check the expiration date (EXP) on the prefilled syringe. <b>Do not</b> use if the expiration date has passed.</li> </ul>

	<ul style="list-style-type: none"> <li>• Check the prefilled syringe for damage, cracks, and leakage. <b>Do not</b> use if any part of the prefilled syringe appears cracked, broken, or is leaking.</li> <li>• Make sure the medicine in the prefilled syringe is clear and colorless to slightly brownish-yellow. It may contain tiny white or clear particles. <b>Do not</b> use if the medicine is cloudy or has flakes or large or colored particles in it.</li> <li>• It is normal to see air bubbles, they do not need to be removed.</li> </ul>
<b>Step 4</b>	<b>Choosing the injection site</b>
	<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 2 inches around your navel (belly button).</li> </ul> </li> <li>• Choose a <b>different injection site</b> each time you inject at least 1 inch away from the last injection site. Alternate between upper thigh or stomach-area for each complete dose.</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>
<b>Step 5</b>	<b>Clean the injection site</b>
	<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>
<b>Step 6</b>	<b>Removing the cap from the prefilled syringe</b>
	<ul style="list-style-type: none"> <li>• Hold the prefilled 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>• Throw away the cap. See Step 9: <b>“Disposing of the used SPEVIGO prefilled syringes and caps.”</b></li> <li>• Proceed to the next step 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.</li> <li>• <b>Do not</b> let go until your injection is complete. See Step 8C: “Checking injection is complete.”</li> </ul>
<p><b>Step 8</b></p>  <p><b>A</b> Inserting the needle</p> <p><b>B</b> Injecting the medicine</p> <p><b>C</b> Checking injection is complete</p>	<p><b>Injecting SPEVIGO</b></p> <p><b>A. Inserting the needle:</b></p> <ul style="list-style-type: none"> <li>• Hold the prefilled syringe by the finger grip.</li> <li>• <b>Do not</b> touch the thumb pad yet.</li> <li>• Using a quick, “dart-like” motion, insert the needle into the pinched skin at about a <b>45-degree</b> angle.</li> <li>• <b>Do not</b> move the needle while inserting or during the injection.</li> </ul> <p><b>B. Injecting the medicine:</b></p> <ul style="list-style-type: none"> <li>• Use your thumb to slowly press down on the thumb pad to push the plunger rod down inside the syringe body.</li> <li>• Continue pressing on the thumb pad until the plunger rod has moved all the way down.</li> <li>• Make sure that the thumb pad cannot be pressed any further so that you can <b>activate the built-in safety cover</b>.</li> </ul> <p><b>C. Checking injection is complete:</b></p> <ul style="list-style-type: none"> <li>• <b>Slowly remove your thumb</b> from the 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 healthcare provider. 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 an adhesive bandage if needed.</li> </ul> <p><b>Important: Do not</b> move the prefilled syringe when inserting the needle into your skin, while injecting, or when removing the needle from your skin.</p>

<b>Step 9</b>	<b>Throwing away (disposing of) the used SPEVIGO prefilled syringe and cap</b>
	<ul style="list-style-type: none"> <li>• Put the used prefilled syringe and cap in an FDA-cleared sharps disposal container right away after use.</li> <li>• If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: <ul style="list-style-type: none"> <li>○ made of a heavy-duty plastic,</li> <li>○ can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,</li> <li>○ upright and stable during use,</li> <li>○ leak resistant, and</li> <li>○ properly labeled to warn of hazardous waste inside the container.</li> </ul> </li> </ul> <p>When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>.</p> <ul style="list-style-type: none"> <li>• <b>Do not</b> reuse the prefilled syringe.</li> <li>• <b>Do not</b> throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this.</li> <li>• <b>Do not</b> recycle your used sharps disposal container.</li> </ul> <p><b>Important:</b> Always keep the sharps disposal container out of the reach of children.</p>
<p>If you have any problems with your injection, do not use another SPEVIGO prefilled syringe. Call your healthcare provider or pharmacist for help.</p> <p><b>For more information call 1-833-SPEVIGO.</b></p>	

Manufactured by: LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Denmark  
Distributed by: LEO Pharma Inc., Madison, NJ 07940, USA  
U.S. License No. 2169

SPEVIGO® is a registered trademark of LEO Pharma A/S.  
© 2026 LEO Pharma Inc. All rights reserved.

For more information about SPEVIGO, including current prescribing information and Medication Guide, go to [www.SPEVIGO.com](http://www.SPEVIGO.com), or call LEO Pharma, Inc. at 1-833-SPEVIGO.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.  
Revised: 03/2026

**INSTRUCTIONS FOR USE**  
**SPEVIGO® (spea VEE go)**  
**(spesolimab-sbzo)**  
**injection, for subcutaneous use**  
**300 mg/2 mL**

**Two 300 mg/2 mL single-dose prefilled syringes for a total of 600 mg dose**

This Instructions for Use contains information on how to inject SPEVIGO.

Read **both sides** of this Instructions for Use before you use SPEVIGO for the first time and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment. Your healthcare provider should show you or your child the right way to inject SPEVIGO before you try to inject yourself or your child for the first time. In children 12 years of age and older, SPEVIGO should be given under the supervision of an adult.

SPEVIGO is for one-time use only. **Do not** reuse the prefilled syringes.

Your healthcare provider has prescribed a dose of SPEVIGO for you or your child that requires 2 injections (2 prefilled syringes) to deliver a complete dose.

**You must inject the contents of both SPEVIGO prefilled syringes that come in the carton to deliver the complete dose.**

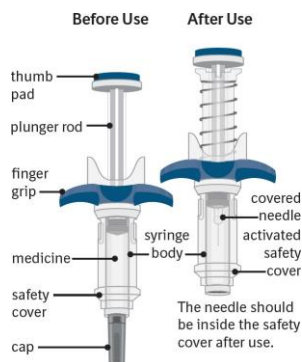


**Getting to know SPEVIGO:**

SPEVIGO comes in a prefilled syringe with a safety cover. The needle is pulled back into the safety cover after injection.

**Guide to parts:**

The figure below shows SPEVIGO before use, and after use with the activated safety cover.



## Important information you need to know before injecting SPEVIGO

- **You must inject the contents of both SPEVIGO prefilled syringes to deliver a complete dose.**
- Inspect the SPEVIGO carton to be sure that you have the correct medicine, 2 prefilled syringes for your or your child's prescribed dose, for any damage, and the expiration date (EXP).
- **Do not** use SPEVIGO if the liquid is cloudy or contains flakes or large or colored particles.
- **Do not** use SPEVIGO if the **expiration date (EXP)** has passed.
- **Do not** use SPEVIGO if the prefilled syringe has been dropped.
- **Do not** remove the cap until you are ready to inject.
- 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.

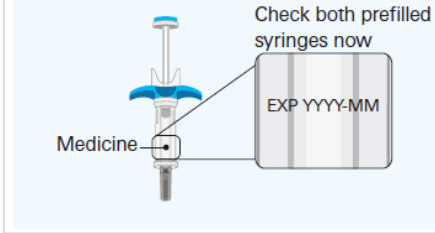
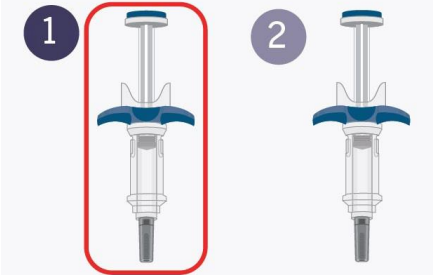
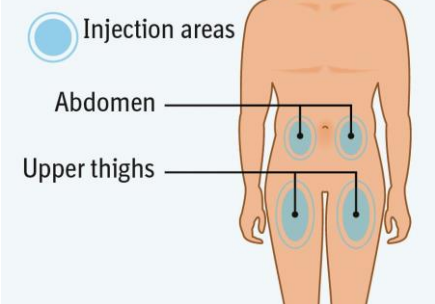
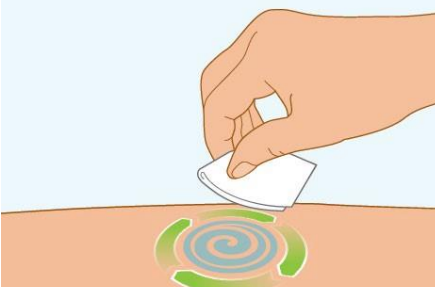

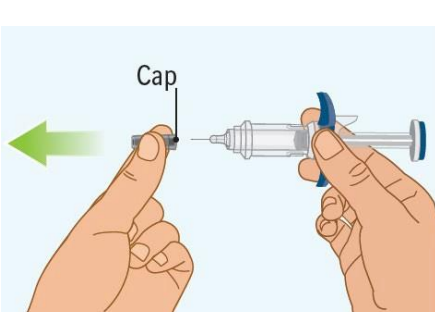
## Storing SPEVIGO

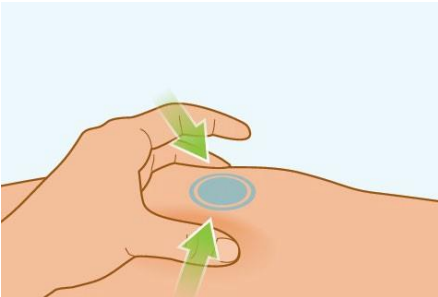



- Store SPEVIGO prefilled syringes in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze SPEVIGO. **Do not** use SPEVIGO if frozen, even if it has been thawed.
- Store SPEVIGO in the original carton until use to protect from light.
- If needed, SPEVIGO 300 mg/2 mL prefilled syringe may also be stored at room temperature up to 77°F (25°C) for up to 14 days.
- Throw away (dispose of) SPEVIGO 300 mg/2 mL prefilled syringe that has been left at room temperature for more than 14 days.

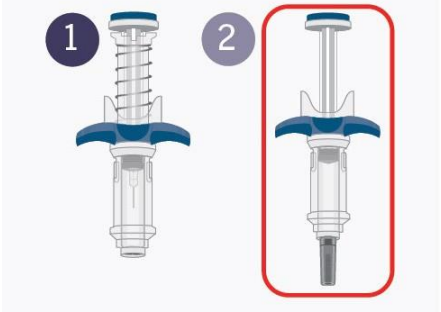
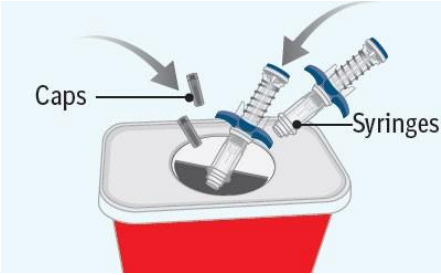


## Keep SPEVIGO and all medicines out of the reach of children.

<p><b>Step 1</b></p> <p>2 SPEVIGO Prefilled syringes</p> <p>2 Cotton balls or gauze (not included)</p> <p>2 Alcohol wipes (not included)</p> <p>Sharps container (not included)</p>	<p><b>Gather supplies</b></p> <ul style="list-style-type: none"> <li>• Take the SPEVIGO carton out of the refrigerator and remove the prefilled syringes from the carton.</li> <li>• Gather supplies listed above 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 above, contact your pharmacist.</li> </ul> <p>• See Step 10: “<b>Disposing of the used SPEVIGO prefilled syringes and caps.</b>”</p>
<p><b>Step 2</b></p> <p>Bring medicine to room temperature</p> <p>15-30 minutes</p> <p>Wash hands</p>	<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.</li> <li>• <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 prefilled syringe in direct sunlight.</li> <li>• <b>Do not</b> remove the needle cap until you are ready to inject.</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 prefilled syringes</b></p> <p><b>Check both prefilled syringes now:</b></p>

	<ul style="list-style-type: none"> <li>• Check to make sure the medicine name SPEVIGO and the dose on your prefilled syringes match your or your child's prescribed dose.</li> <li>• Check the expiration date (EXP) on both prefilled syringes. <b>Do not</b> use if the expiration date has passed.</li> <li>• Check both prefilled syringes for damage, cracks, and leakage. <b>Do not</b> use if any part of the prefilled syringes appear cracked, broken, or are leaking.</li> <li>• Make sure the medicine in both prefilled syringes is clear and colorless to slightly brownish-yellow. It may contain tiny white or clear particles. <b>Do not</b> use if the medicine is cloudy or has flakes or large or colored particles in it.</li> <li>• It is normal to see air bubbles, they do not need to be removed.</li> </ul>
<p><b>Preparing for your first injection</b></p>	
	<p><b>Prepare for the first of 2 injections.</b></p> <p><b>You will repeat the following steps with the second syringe right away after your first injection.</b></p> <p><b>2 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 2 inches around your navel (belly button).</li> </ul> </li> <li>• Choose a <b>different injection site</b> each time you inject, at least 1 inch away from the last injection site. Alternate between upper thigh or stomach-area for each complete dose.</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>Clean 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 from the prefilled syringe</b></p>
	<ul style="list-style-type: none"> <li>• Hold the prefilled 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>• Throw away the cap. See Step 10: “<b>Disposing of the used SPEVIGO prefilled syringes and caps.</b>”</li> </ul>

	<ul style="list-style-type: none"> <li>Proceed to the next step 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>
<b>Step 7</b>	<b>Pinch the skin</b>
	<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.</li> <li><b>Do not</b> let go until your injection is complete. See Step 8C: <b>“Checking injection is complete.”</b></li> </ul>
<b>Step 8</b>	<b>Injecting SPEVIGO</b>
 <p><b>A</b> Inserting the needle</p>	<p><b>A. Inserting the needle:</b></p> <ul style="list-style-type: none"> <li>Hold the prefilled syringe by the finger grip.</li> <li><b>Do not</b> touch the thumb pad yet.</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>Push Firmly</p> <p><b>B</b> Injecting the medicine</p>	<p><b>B. Injecting the medicine:</b></p> <ul style="list-style-type: none"> <li>Use your thumb to slowly press down on the thumb pad to push the plunger rod down inside the syringe body.</li> <li>Continue pressing on the thumb pad until the plunger rod has moved all the way down.</li> <li>Make sure that the thumb pad cannot be pressed any further so that <b>you can activate the built-in safety cover</b>.</li> </ul>
 <p>Remove thumb to activate safety cover</p> <p><b>C</b> Checking injection is complete</p>	<p><b>C. Checking injection is complete:</b></p> <ul style="list-style-type: none"> <li><b>Slowly remove your thumb</b> from the 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 healthcare provider. 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 an adhesive bandage if needed.</li> </ul>
	<p><b>Important: Do not</b> move the prefilled syringe when inserting the needle into your skin, while injecting, or when removing the needle from your skin.</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 1 inch away from last injection site. Alternate between upper thigh or stomach-area for each complete dose.</li> <li>• <b>Get second prefilled 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></p> <p><b>You must inject the contents of both SPEVIGO prefilled syringes to give a complete dose.</b></p>
<p><b>Step 10</b></p> 	<p><b>Throwing away (disposing of) the used SPEVIGO prefilled syringes and caps</b></p> <ul style="list-style-type: none"> <li>• Put the used prefilled syringes and caps in an FDA-cleared sharps disposal container right away after use.</li> <li>• If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: <ul style="list-style-type: none"> <li>○ made of a heavy-duty plastic,</li> <li>○ can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,</li> <li>○ upright and stable during use,</li> <li>○ leak resistant, and</li> <li>○ properly labeled to warn of hazardous waste inside the container.</li> </ul> </li> </ul> <p>When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>.</p> <ul style="list-style-type: none"> <li>• <b>Do not</b> reuse the prefilled syringes.</li> <li>• <b>Do not</b> throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this.</li> <li>• <b>Do not</b> recycle your used sharps disposal container.</li> </ul> <p><b>Important:</b> Always keep the sharps disposal container out of the reach of children.</p>
<p>If you have any problems with your injection, do not use another SPEVIGO prefilled syringe. Call your healthcare provider or pharmacist for help.</p> <p><b>For more information call 1-833-SPEVIGO.</b></p>	

Manufactured by: LEO Pharma A/S Industriparken 55, DK-2750 Ballerup, Denmark  
Distributed by: LEO Pharma Inc., Madison, NJ 07940, USA  
U.S. License No. 2169

SPEVIGO® is a registered trademark of LEO Pharma A/S.  
© 2026 LEO Pharma Inc. All rights reserved.

For more information about SPEVIGO, including current prescribing information and Medication Guide, go to [www.SPEVIGO.com](http://www.SPEVIGO.com), or call LEO Pharma, Inc. at 1-833-SPEVIGO.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.  
Issued: 03/2026