INSTRUCTIONS FOR USE VOYXACT® (VOY-ZAKT)

(sibeprenlimab-szsi)
injection, for subcutaneous use
Single-Dose Prefilled Syringe

This Instructions for Use contains information on how to inject VOYXACT. Read and follow this Instructions for Use before you inject VOYXACT prefilled syringe for the first time and each time you get a refill. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Your healthcare provider should show you or your caregiver how to prepare and inject VOYXACT the right way before you use or give it for the first time.

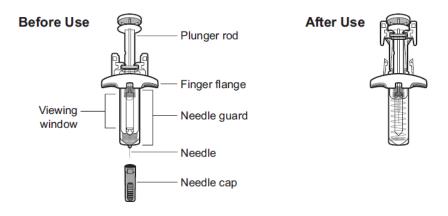
Important Information You Need to Know Before Injecting VOYXACT Prefilled Syringe

- VOYXACT prefilled syringe is for injection under the skin (subcutaneous injection) use only.
- Do not remove the grey needle cap from the prefilled syringe until you are ready to inject.
- Each prefilled syringe has a needle guard. It will automatically cover the needle after the injection is completed.
- Do not pull back on the plunger at any time.
- Do not use if the VOYXACT prefilled syringe has been damaged.
- **Do not** use if the VOYXACT prefilled syringe has been dropped after removing the needle cap.

Storing VOYXACT Prefilled Syringe

- Store your VOYXACT prefilled syringe in a refrigerator between 36°F to 46°F (2°C to 8°C). Keep the prefilled syringe in its original box to protect it from light.
- Let the VOYXACT prefilled syringe come to room temperature up to 77°F (25°C) for 15 to 30 minutes before giving an injection.
- When the VOYXACT prefilled syringe has reached room temperature, **do not** put it back in the refrigerator.
- Do not use the VOYXACT prefilled syringe if it has been at room temperature for 7 days or longer.
- Do not freeze the VOYXACT prefilled syringe.
- Do not shake the VOYXACT prefilled syringe.
- **Keep** the VOYXACT prefilled syringe away from heat and direct sunlight.
- Throw away (dispose of) any VOYXACT prefilled syringe if it is expired. See Step 11 for instructions on how to throw away (dispose of) the VOYXACT prefilled syringe.
- Keep VOYXACT prefilled syringe and all medicines out of the reach of children.

Your VOYXACT Single-Dose Prefilled Syringe



Getting Your Supplies Ready

Step 1: Remove the VOYXACT prefilled syringe box from the refrigerator

Take the box containing VOYXACT prefilled syringe out of the refrigerator and check the expiration date (EXP) on the side of the box.

- **Do not** use the prefilled syringe if the seals on the box have been broken.
- **Do not** use the prefilled syringe if the expiration date (EXP) printed on the box has passed.

Step 2: Wait 15 to 30 minutes before use

Wait 15 to 30 minutes to let the prefilled syringe come to room temperature naturally (see Figure A).

- **Do not** warm the prefilled syringe any other way.
- **Do not** let the prefilled syringe sit in direct sunlight.

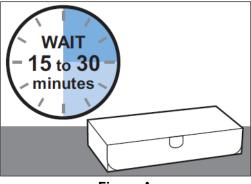
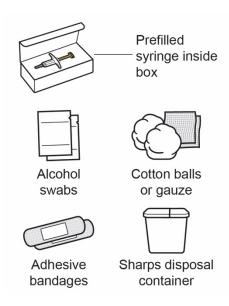


Figure A

Step 3: Gather supplies

Gather supplies that are not included in the VOYXACT prefilled syringe box:

- Alcohol swabs
- · Cotton balls or gauze
- Adhesive bandages
- Sharps disposal container (see Step 11)



Preparing to Inject the VOYXACT Prefilled Syringe

Step 4: Take the VOYXACT prefilled syringe out of the box

Hold the middle of the prefilled syringe (near the viewing window) to carefully lift the prefilled syringe out of the box (see **Figure B**).

- **Do not** lift the prefilled syringe by the plunger.
- Do not shake or roll the prefilled syringe.
- Do not remove the grey needle cap from the prefilled syringe until Step 8 and you are ready to inject.

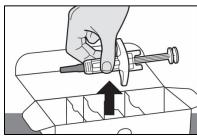


Figure B

Step 5: Inspect the VOYXACT Prefilled Syringe

- Make sure that VOYXACT appears on the labels.
- Check the expiration date (EXP) printed on the prefilled syringe (see Figure C).
- Check the medicine in the prefilled syringe through the viewing window. It is normal to see air bubbles. The medicine inside should be clear to slightly pearly and colorless to yellow (see **Figure C**).
- Do not use VOYXACT prefilled syringe if:
 - the expiration date printed on the prefilled syringe label has passed.
 - the medicine is cloudy, discolored, or has particles floating in it.
 - any part of the prefilled syringe is damaged, broken, or the needle guard has been activated.
- Do not try to remove air bubble(s) from the prefilled syringe.

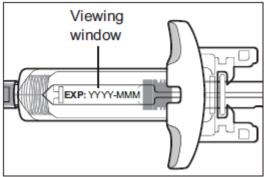


Figure C

Step 6: Choose the injection site

Choose an injection site on your bare skin from 1 of the following areas (see **Figure D**):

- front of upper thigh
- stomach area (abdomen), avoiding the area 2 inches around the belly button.
 For caregiver only: back of the upper arm may also be used.
- Do not inject into the same spot you used for your last injection.
- **Do not** inject into moles, scars, or bruises or skin that is tender, damaged, hard or red.

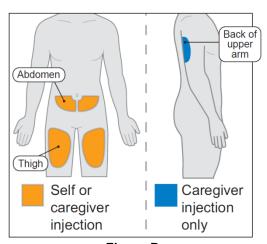


Figure D

Step 7: Clean the injection site

Wash your hands with soap and clean water (see Figure E).

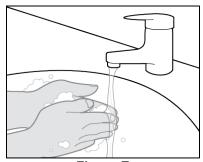


Figure E

- Clean the injection site with an alcohol swab and let the skin dry (see **Figure F**).
- Do not touch the area again before injecting.

Do not fan or blow on the injection site after you have cleaned it.

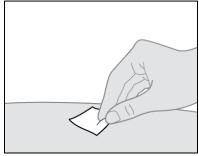


Figure F

Injecting VOYXACT

Step 8: Remove the needle cap

When you are ready to inject, hold the prefilled syringe with 1 hand, pull the needle cap straight off with the other hand (see **Figure G**).

- You may see a drop of liquid at the end of the needle. This is normal.
- Do not touch or recap the needle or let it touch any surface.
- Do not touch or pull back the plunger.
- **Do not** use a prefilled syringe with a bent or broken needle.

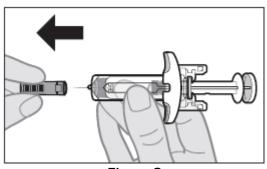


Figure G

Step 9: Pinch the skin and insert needle

With the needle cap off, hold the prefilled syringe in 1 hand. With your other hand, gently pinch the skin at the injection site (see **Figure H**).

• It is important to pinch enough skin to inject under the skin and not into the muscle.

Insert the entire needle at a 45-degree angle into the pinched skin using a dart-like motion (see Figure H).

• Avoid touching the plunger until the needle is inserted.

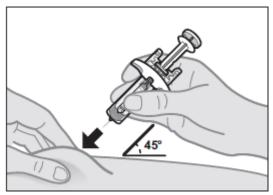


Figure H

Step 10: Complete the Injection

Push the plunger as far as it will go and it stops, and all the medicine is injected (see **Figure I**).

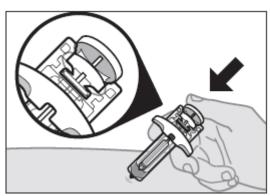


Figure I

Take your thumb off the plunger to allow the needle guard to automatically cover the exposed needle (see **Figure J**).

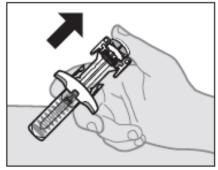


Figure J

Gently lift the syringe away from the injection site (see **Figure K**).

- There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze until any bleeding stops.
- Apply an adhesive bandage, if needed.
- **Do not** rub or massage the injection site.

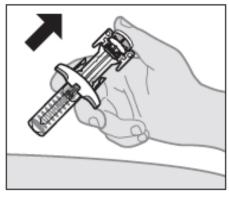


Figure K

Disposing of the VOYXACT Prefilled Syringe

Step 11: Throw away (dispose of) the VOYXACT prefilled syringe

Throw away (dispose of) the used prefilled syringe in a FDA-cleared sharps disposal container right away after use (see **Figure L**). **Do not** recycle or throw away the prefilled syringe in your household trash.



Figure L

- Throw away the remaining supplies in your household trash or sharps container.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.
- 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 local or state laws about
 how to throw away 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: http://www.fda.gov/safesharpsdisposal.
- Do not recycle your used sharps disposal container.

If you have questions or concerns about your VOYXACT prefilled syringe, please call your healthcare provider. You can also call 1-800-441-6763 or visit www.VOYXACT.com for more information.

Manufactured by: Otsuka Pharmaceutical Company, Ltd.

Tokyo 101-8535 Japan U.S. License No 2387

Distributed by: Otsuka America Pharmaceutical, Inc. Rockville, MD 20850 USA

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

21US25IBR0005

Issued: Nov 2025