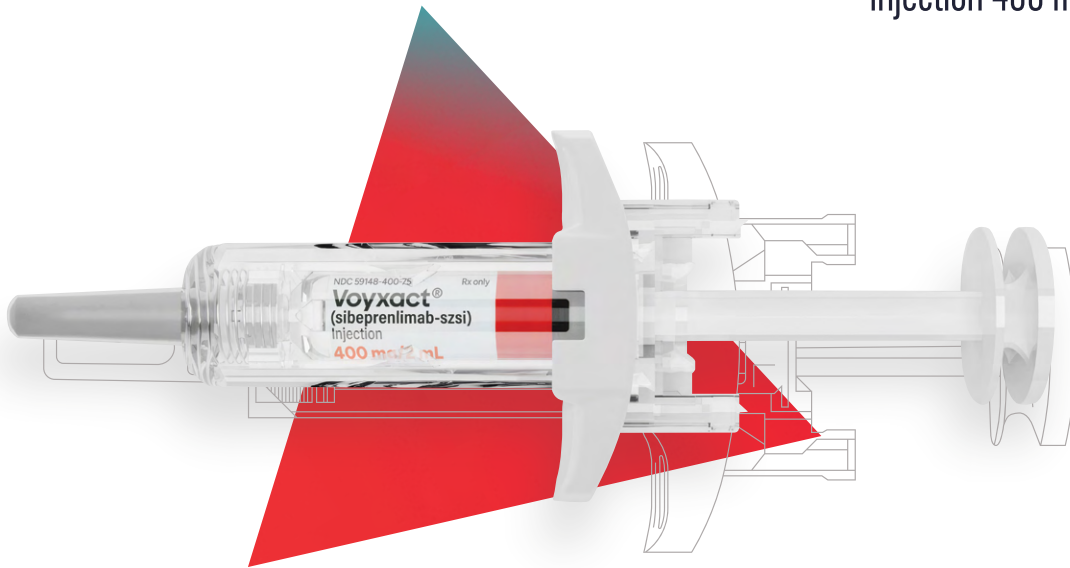




**Voyxact<sup>®</sup>**  
(sibeprenlimab-szsi)  
Injection 400 mg/2 mL



# VOYXACT<sup>®</sup> DOSING & ADMINISTRATION GUIDE

**This dosing and administration guide for VOYXACT provides important dosing information along with clear, step-by-step administration instructions.**

Supportive visuals and QR codes that link to the corresponding steps in the injection training video help ensure VOYXACT is used safely and correctly every time.



Scan the QR code to watch the injection training video or [click here](#).

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Please see [Important Safety Information on page 7](#) and full [Prescribing Information, including Patient Information](#).





Storing  
VOYXACT  
Prefilled Syringe



Getting Your  
Supplies Ready



Preparing to  
Inject VOYXACT  
Prefilled Syringe



Injecting  
VOYXACT  
Prefilled Syringe



Disposing of  
the VOYXACT  
Prefilled Syringe

# INSTRUCTIONS FOR USE

## VOYXACT® (VOY-ZAKT) (sibeprenlimab-szsi) injection, for subcutaneous use

### Single-Dose Prefilled Syringe

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** 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.**



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THIS SECTION  
OR [CLICK HERE](#).

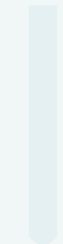
Please see **Important Safety Information on page 7**  
and full **Prescribing Information, including Patient Information.**



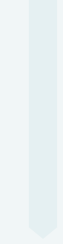
Storing VOYXACT Prefilled Syringe



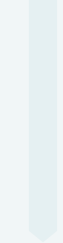
Getting Your Supplies Ready



Preparing to Inject VOYXACT Prefilled Syringe

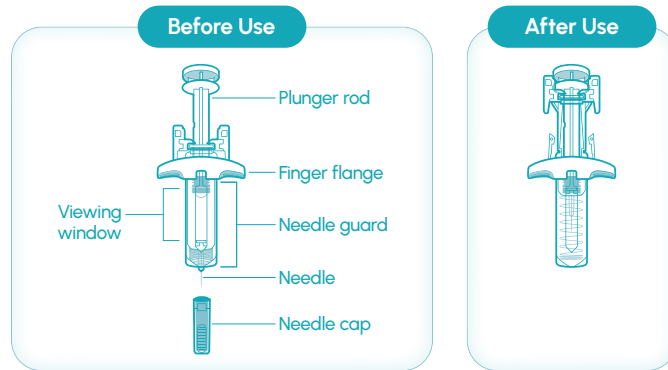


Injecting VOYXACT Prefilled Syringe



Disposing of the VOYXACT Prefilled Syringe

## Your VOYXACT Single-Dose Prefilled Syringe



### Getting Your Supplies Ready



SCAN TO WATCH THIS SECTION OR [CLICK HERE](#).

#### 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.

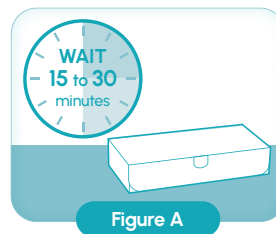


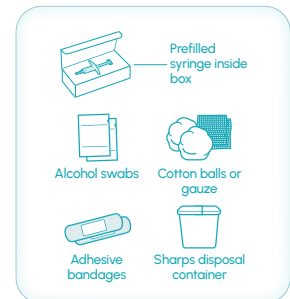
Figure A

#### 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**)



Please see **Important Safety Information** on [page 7](#) and full [Prescribing Information](#), including [Patient Information](#).



Storing  
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Preparing to  
Inject VOYXACT  
Prefilled Syringe



Injecting  
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## Preparing to Inject the VOYXACT Prefilled Syringe



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### 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.

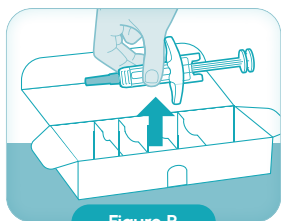


Figure B

### 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.

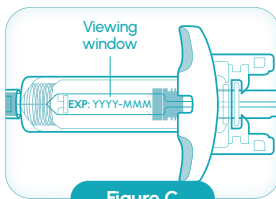


Figure C

### 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.

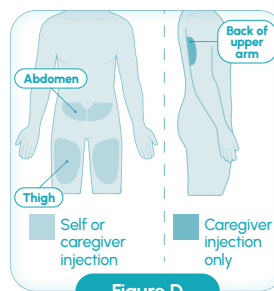


Figure D

### Step 7:

#### Clean the injection site

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

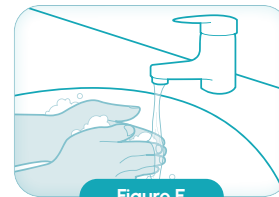


Figure E

- Clean the injection site with an alcohol swab and let 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.

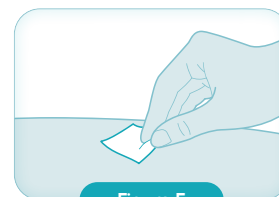


Figure F

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Storing VOYXACT Prefilled Syringe

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Disposing of the VOYXACT Prefilled Syringe

**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.

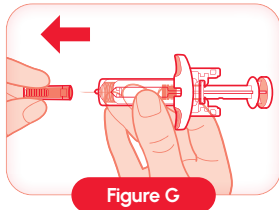


Figure G

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

- **Avoid** touching the plunger until the needle is inserted.

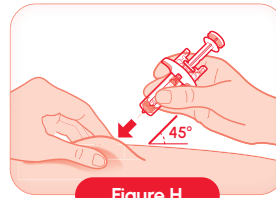


Figure H

**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**).

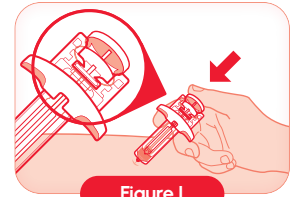


Figure I

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

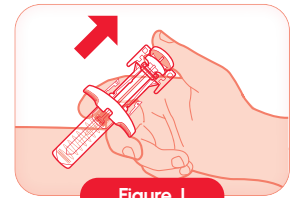


Figure J

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.

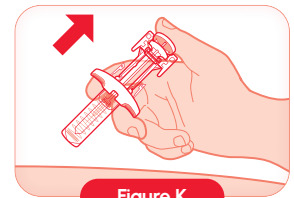


Figure K

Please see **Important Safety Information** on [page 7](#) and full **Prescribing Information**, including **Patient Information**.



Storing  
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Getting Your  
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Injecting  
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Disposing of  
the VOYXACT  
Prefilled Syringe

## Disposing of the VOYXACT Prefilled Syringe



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### 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.

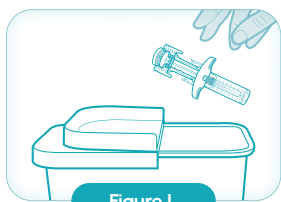


Figure L

- 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](http://www.VOYXACT.com) for more information.

Manufactured by:  
Otsuka Pharmaceutical Co., Ltd.  
Tokyo 101-8535 Japan  
U.S. License No 2387

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

### VOYXACT DOSING

VOYXACT is a 400 mg/2 mL self-administered injection in a single-dose prefilled syringe. It is given once every 4 weeks as a subcutaneous (under the skin) injection.

### WHAT TO DO IF A DOSE IS MISSED

If a scheduled dose of VOYXACT is missed, administer the missed dose as soon as possible and then resume every 4 weeks thereafter.

Please see [Important Safety Information on page 7](#) and full [Prescribing Information](#), including [Patient Information](#).



**INDICATION and IMPORTANT SAFETY INFORMATION for VOYXACT® (sibeprenlimab-szsi)**

**INDICATION**

VOYXACT is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at risk for their disease getting worse. It is not known if VOYXACT is safe and effective in children.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about VOYXACT?**

- **Do not take VOYXACT if you** are allergic to any of the ingredients in VOYXACT. Stop using VOYXACT and get emergency help if you develop signs and symptoms of an allergic reaction, including:
  - breathing problems
  - swelling of the face, lips, mouth, tongue or throat
  - dizziness or feel lightheaded
  - itching
  - hives
  - skin rash

**Before taking VOYXACT, tell your healthcare provider about all of your medical conditions, including if you:**

- have an infection.
- have received or plan to receive therapy that can lower the ability of your immune system to fight infections (immunosuppressive therapy).
- have recently received or are scheduled to receive an immunization (vaccine). VOYXACT may affect your immune system response to vaccines and increase your risk of infections from live vaccines.

- are pregnant or plan to become pregnant. It is not known if VOYXACT will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VOYXACT passes into your breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with VOYXACT.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I take VOYXACT?**

- **Read the detailed "Instructions for Use"** that come with VOYXACT for information about how to prepare and inject VOYXACT, and how to properly store and throw away (dispose of) used VOYXACT prefilled syringes.
- Use VOYXACT exactly as your healthcare provider tells you to.
- If you miss a dose of VOYXACT, inject the missed dose as soon as possible. Then take your next dose in 4 weeks.

**What are the possible side effects of VOYXACT?**

VOYXACT can cause serious side effects, including:

- **immunosuppression and increased risk of infections.** VOYXACT weakens your immune system, which may increase your risk of infections. Your healthcare provider will check you for signs and symptoms of infections before you start and during treatment with VOYXACT. Tell your healthcare provider right away if you develop any signs and symptoms of infection during treatment with VOYXACT, including:
  - fever
  - chills
  - feeling tired
  - cough
  - flu-like symptoms
  - aches and pain
  - warm, red, or painful skin

**The most common side effects of VOYXACT include:**

upper respiratory tract infection and skin redness at your injection site.

These are not all of the possible side effects of VOYXACT.

Call your doctor for medical advice about side effects. You are encouraged to report side effects to FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see full Prescribing Information and Patient Information.**

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