

INSTRUCTIONS FOR USE

**VOXZOGO™ [Vox zoe' goe]
(vosoritide)**

**for injection, for subcutaneous use
Single-Use**

This Instructions for Use contains information for caregivers on how to inject VOXZOGO.

Read this Instructions for Use before you start using VOXZOGO and each time you get a refill. There may be new information. This information does not take the place of talking to your child's healthcare provider about your child's medical condition and their treatment. Before you use VOXZOGO for the first time, make sure your child's healthcare provider shows you the right way to use it. Contact your child's healthcare provider if you or your child have any questions.

Important Information You Need to Know Before Injecting VOXZOGO

- **Wash your hands** with soap and water.
- **Do not** drop VOXZOGO or put opened items down on surfaces that are not clean.
- VOXZOGO is available in more than 1 strength. **Make sure the strength matches your prescription strength. Do not** open packaging until ready to use.
- Take the VOXZOGO vial and prefilled diluent syringe out of the refrigerator and allow them to reach room temperature before mixing.
- **Inspect the vial and supplies for any signs of damage or contamination. Do not** use if damaged or contaminated.
- **Check the expiration date.** The expiration date can be found on the carton, vial and prefilled diluent syringe. **Do not** use if expired.
- **Your child should eat a meal and drink a glass (about 8 to 10 ounces) of fluid (such as water, milk, or juice) within 1 hour before injection.**
- **VOXZOGO should be given at about the same time every day.**
- Do not mix VOXZOGO with other medicines.
- **After mixing the VOXZOGO, use it right away. Do not** use the mixed VOXZOGO if it has been sitting at room temperature for more than 3 hours. Throw it away (dispose of) in a sharps container. **See** step 18 and **“How to Throw Away (Dispose of) VOXZOGO”** for more information.
- **Do not reuse any of the supplies. After the injection, throw away (dispose of) the used vial even if there is VOXZOGO remaining. See** step 18 and **“How to Throw Away (Dispose of) VOXZOGO”** for more information.

How to Store VOXZOGO

- Store the VOXZOGO vial and prefilled diluent syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- You may store VOXZOGO (before mixing) at room temperature between 68°F to 77°F (20°C to 25°C) for 90 days. Record the date you started storing VOXZOGO at room temperature on the carton to keep track of the 90 days. **Do not** return VOXZOGO to the refrigerator after it has been stored at room temperature. Throw VOXZOGO away if unused within 90 days of storing at room temperature.
- **Do not** freeze VOXZOGO.
- Store VOXZOGO out of direct sunlight.

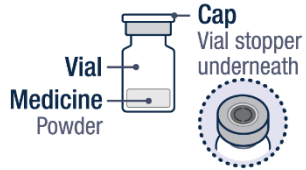
Keep VOXZOGO and all other medicines out of the reach of children.

Supplies Needed to Inject VOXZOGO

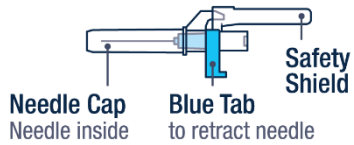
Gather all of these supplies on a clean, flat surface before injecting.

Items supplied

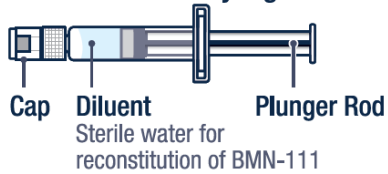
VOXZOGO



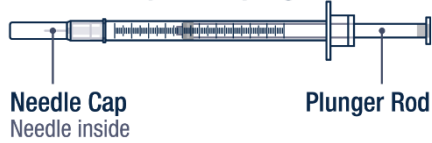
Diluent Needle



Prefilled Diluent Syringe



Injection Syringe



Items not supplied

If you do not have these items, ask your pharmacist.

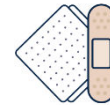
Alcohol Pads



Sharps Container



Gauze or Bandage



Preparing VOXZOGO for Injection

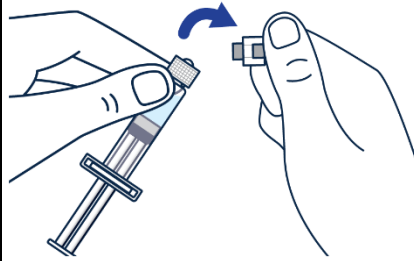
► Step 1

On a clean flat surface, flip off the vial cap and wipe the top with an alcohol pad.



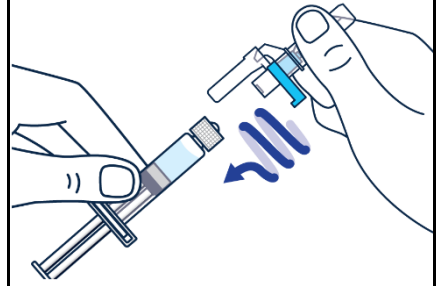
► Step 2

Gently bend to snap off the cap from the prefilled diluent syringe.



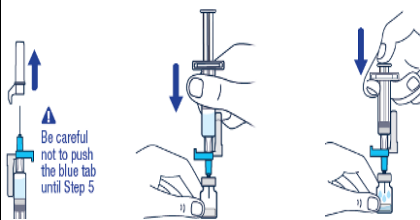
► Step 3

Twist the diluent needle onto the prefilled diluent syringe until you can no longer twist it. Do not use the prefilled diluent syringe to give the injection.



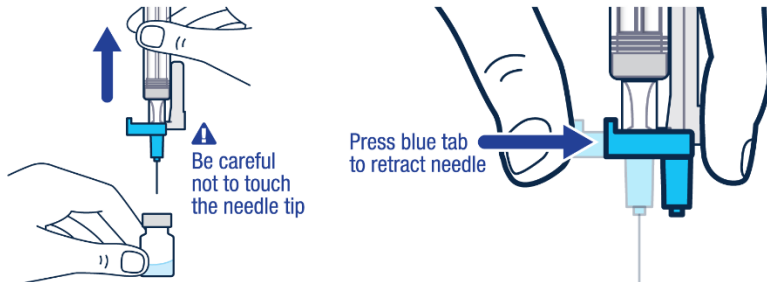
► Step 4

Pull off the needle cap and insert the needle through the middle of the vial stopper. Slowly push the plunger rod down to inject all of the liquid.



► Step 5

Remove the needle from the vial, then press the blue tab for the needle to pull back (retract). Throw away the needle and syringe in a sharps container. See step 18 and "How to Throw Away (Dispose of) VOXZOGO." Do not use the prefilled diluent syringe to give the injection.



► **Step 6**

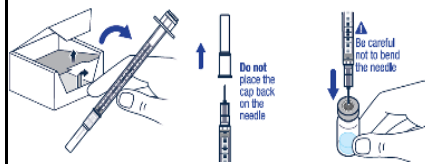
Gently swirl the vial until the powder has completely dissolved and the solution is clear. **Do not shake.**



Make sure medicine is clear to yellow, not cloudy and does not have particles.

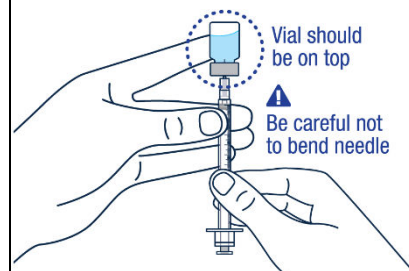
► **Step 7**

Take the injection syringe out of the carton. **Pull off** the needle cap from the injection syringe **and insert the needle straight** through the **middle** of the vial stopper. Be careful not to bend the needle.



► **Step 8**

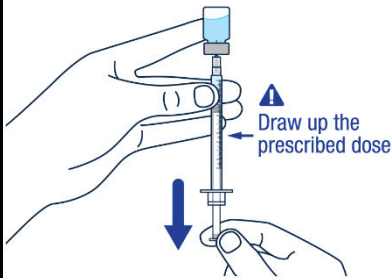
Carefully hold the vial and syringe and turn the vial upside down with the needle still inserted. The vial should be on top. Be careful not to bend the needle.



Preparing VOXZOGO for Injection (continued)

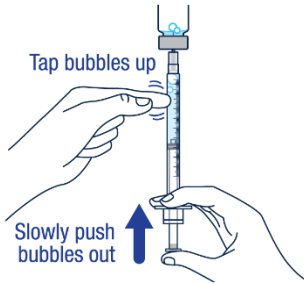
► Step 9

Keep the needle tip in the medicine and slowly pull the plunger rod back to draw up the prescribed dose in the syringe. Check the prescription label for how much to draw up.



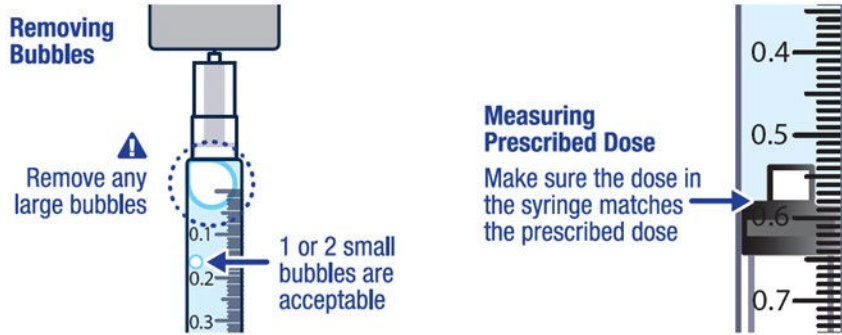
► Step 10

Remove large air bubbles in the syringe by gently tapping the syringe. Then push the bubbles back into the vial.



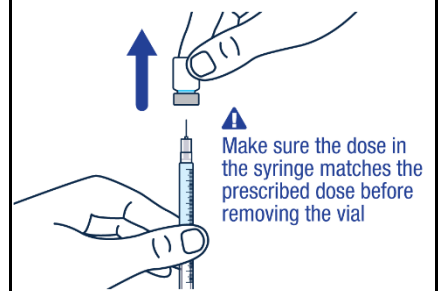
► Step 11

Repeat steps 9 and 10 until you have the correct prescribed dose in the syringe and no large bubbles.



► Step 12

Make sure you have the prescribed dose in the syringe, then remove the vial and prepare to give the dose.



Select and Prepare Injection Site

► Step 13

VOXZOGO should be injected into the fatty layer under the skin (subcutaneous) only.

Do not inject into the same site 2 times in a row.

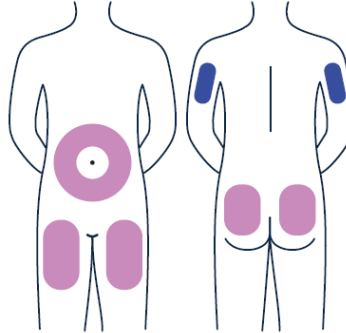


Do not inject through clothes.

Do not inject into skin that is swollen, sore, bruised, red, hard, or scarred.


The following sites are recommended for injection:

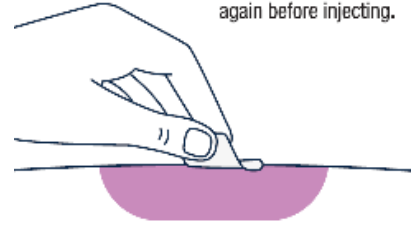
- **Thighs** or
- **Abdomen** (2 inches from belly button) or
- **Buttocks**
- Healthcare providers and caregivers may also inject VOXZOGO into the **back of the upper arms**.



► Step 14

Wipe the injection site with an alcohol pad and let the skin air dry.

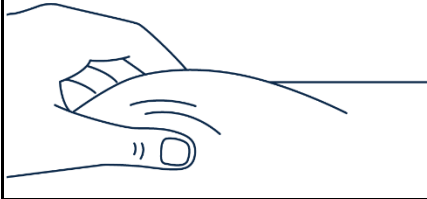
 **Do not** touch the area again before injecting.



Giving VOXZOGO Injection

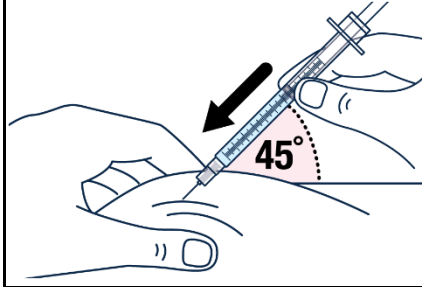
► Step 15

After wiping the site with an alcohol pad, **pinch** the skin up around the selected injection site.



► Step 16

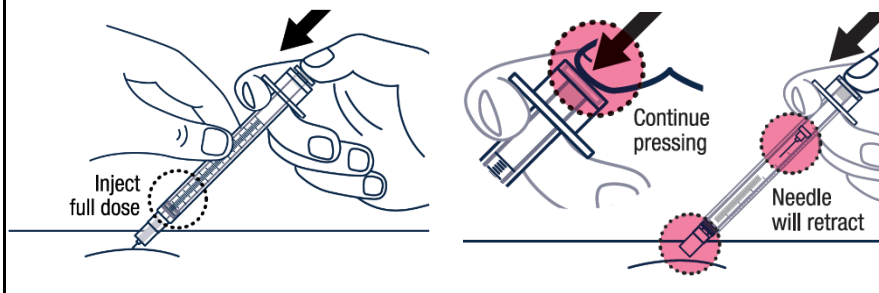
Quickly insert the needle all the way into the skin at a **45-degree angle**.



► Step 17

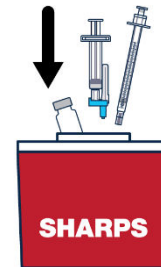
Release the pinch and slowly push the plunger rod all the way down.

Continue pressing the plunger rod until the needle retracts into the syringe.



► Step 18

Throw away the used vial, syringes and needles in a sharps container. See **“How to Throw Away (Dispose of) VOXZOGO”** for more information.



How to Throw Away (Dispose of) VOXZOGO

Put your used or expired vials, needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) the vials, loose needles and syringes in your household trash.**

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,
- is upright and stable during use,
- is leak-resistant, and
- is 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 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:

<http://www.fda.gov/safesharpsdisposal>

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

After the Injection

- Inspect the injection site. If a small amount of bleeding occurs from the injection site, gently press a gauze pad on it for a few seconds or apply a bandage. **Do not** rub the injection site.
- Monitor for signs of low blood pressure, such as dizziness, tiredness, and nausea. If your child experiences these symptoms you should call your child's healthcare provider, then get your child to lay back with legs raised.

For Help or More Information

- Call your healthcare provider
- Call BioMarin at 1-800-123-4567
- Visit www.VOXZOGO.com

Manufactured for:
BioMarin Pharmaceutical Inc.,
Novato, CA 94949

REP-5233-C10

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