VOXZOGO®▼
(vosoritide) for injection

For the treatment of achondroplasia in paediatric patients whose epiphyses are not closed[1]*

Dosing and administration guide

This guide will familiarise you with administration so you can help patients and caregivers feel comfortable with daily injections.

*The diagnosis of achondroplasia should be confirmed by appropriate genetic testing.[1]

This guide is intended for healthcare professionals only.

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

BIOMARIN®

What's In This Guide

Patient Management

Helpful Hints

Before administration

Advise caregivers to find a calm, clean and comfortable place to give their child's injection. It is recommended that the child eats a light snack and drinks a glass of fluid (e.g. water, milk or juice) about 30 minutes before injecting.[1]

Encourage communication between your patient and caregiver after administration

After every injection, it's helpful for the caregiver to have a short talk with their child about how they feel.

Tips for caregivers and families for daily VOXZOGO® administration

VOXZOGO® is registered for daily treatment of paediatric patients through childhood, until their growth plates close.[1] Remind your families to carefully read the Consumer Medicine Information so they can familiarise themselves with all the information they need to administer VOXZOGO® effectively.

Every family is unique. Empower families to incorporate VOXZOGO® into their child's daily routine in a way that's successful for them.

Growth Monitoring and Dose Adjustment[1]

It is your responsibility to adjust the patient's dosage according to their bodyweight. At follow-up appointments remember to weigh the patient and to tell caregivers the correct dose and volume of VOXZOGO® to administer to their child.

Single dose volumes by body weight[1]

Patient weight (kg)	VOXZOGO® 0.4 mg 0.8 mg/mL (0.5 mL solvent)	VOXZOGO® 0.56 mg 0.8 mg/mL (0.7 mL solvent)	VOXZOGO® 1.2 mg 2 mg/mL (0.6 mL solvent)
	DAILY INJECTION VOLUME (mL)		
3	0.12 mL		
4	0.15 mL		
5	0.20 mL		
6-7	0.25 mL		
8-11	0.30 mL		
12-16		0.35 mL	
17-21		0.40 mL	
22-32		0.50 mL	
33-43			0.25 mL
44-59			0.30 mL
60-89			0.35 mL
≥90			0.40 mL

Adjust dose based on body weight

Regular patient follow-up will ensure appropriate dosing from early childhood through teenage years. Assess patient weight every 3 to 6 months to determine the appropriate dose.[1]

Administration Process

Injection Video

Getting Started[1,2]

To help establish a daily routine, encourage caregivers to administer VOXZOGO® at the same time each day. Guiding caregivers through each step can help them feel more organised and prepared for the injection.

Caregivers will need:

1. A **calm and clean** environment where the patient and caregiver feel comfortable.

2. A light **snack and drink** the patient can consume **30 minutes before injection** to reduce the signs and symptoms of potential decreases in blood pressure.

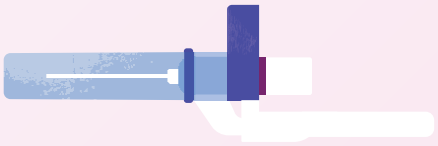
Use this time to let the VOXZOGO® vial reach room temperature.

3. Hands washed with soap and water plus a clean, flat surface or clean placemat to keep everything clearly laid out.

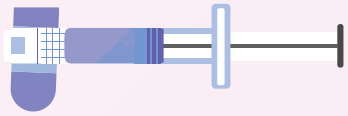
4. A **vial with medicine powder at room temperature**. Show the caregiver how to check the expiry date and inspect for damage or contamination. Any damaged or out-of-date medicine should be discarded in a sharps disposal or puncture-resistant container as per local regulations.

VOXZOGO® comes in 3 strengths, indicated by white, magenta, and grey coloured caps. Dosing is based on weight and may be adjusted as part of regular check-ins every 3 to 6 months. For complete dosing information, refer to the VOXZOGO Product Information.

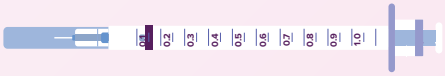
5. The **diluent needle**.



6. The **diluent syringe** containing sterile water at room temperature. Show the caregiver how to check the expiry date and do not use if expired.



7. An **injection syringe** with capped needle.



8. **Alcohol pads, gauze or adhesive bandage and a sharps disposal or puncture-resistant container** (as per local regulations).*

*Items needed, but not supplied in the pack.

Show caregivers how to inspect the vial and materials for any sign of damage or contamination, such as discoloured medicine or bent syringes. Remind them not to use VOXZOGO® or the diluent syringe if they are expired.

Preparing the Injection[2]

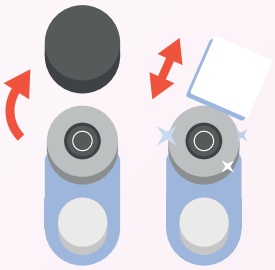
How to mix the sterile water with the medicine powder to prepare the injection syringe

Most caregivers will not be familiar with reconstituting medications, so it is vital they feel comfortable with the following steps.

Step 1

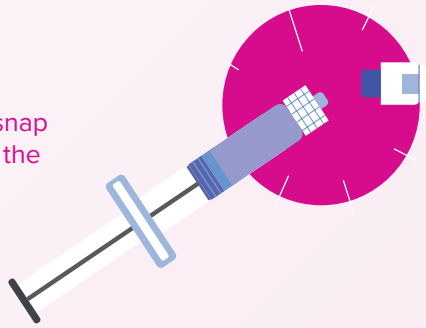
- Begin by demonstrating how to flip off the **vial cap** and wipe the exposed stopper with an alcohol pad

Remind caregivers not to touch the vial stopper once cleaned.



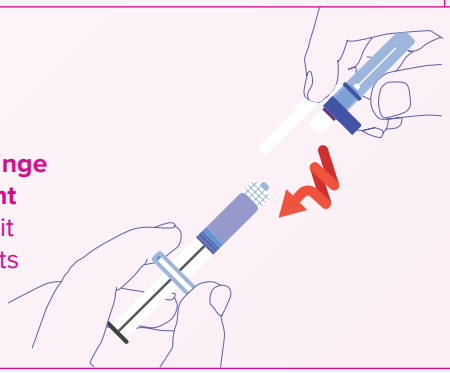
Step 2

- Gently bend to snap off the cap from the **diluent syringe**



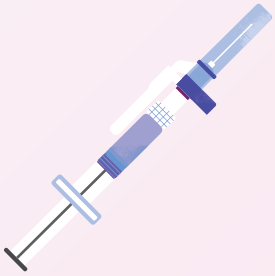
Step 3

- Hold the **solvent syringe** and screw the **solvent *needle*** straight onto it until it no longer twists



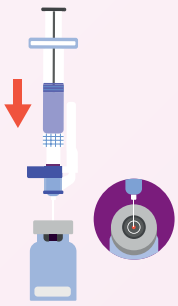
- Make sure the syringe and the needle are tightly attached to prevent leakage

Inform caregivers not to use the solvent syringe to administer the injection.



Step 4

For this next part, emphasise the importance of safe needle handling – make sure caregivers know not to point the needle at anyone, including themselves.



- Explain how to remove the **needle cap** by pulling it straight off while pointing the needle away from anyone
- Insert the **needle** straight down through the middle of the **vial** stopper – **instructing caregivers not to insert at an angle or touch the side walls**

- ***Slowly*** push the plunger rod down to inject all of the **sterile water** into the vial. Pushing too quickly will cause air bubbles

Step 5

Make sure caregivers are careful not to push the blue tab until all the sterile water is in the vial or the needle will retract too soon.

- Once there is no more **sterile water** in the syringe, remove the **diluent needle** from the **vial**
- Press the blue tab to retract the **needle**

- Instruct caregivers to dispose of the used **solvent needle** and **syringe** in the **sharps container**

Preparing the Injection (continued)[2]

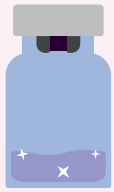
Step 6

- ***Gently*** swirl the **vial** until the powder is completely dissolved and the solution is clear

Remind caregivers not to shake the vial or touch the vial stopper.

- Examine the **vial** to make sure the medicine is:
  - clear to yellow
  - not cloudy
  - does not contain particles

Instruct caregivers to discard the vial if the medicine looks cloudy, discoloured, or contaminated with particles. Once mixed, the medicine must be used within 3 hours.

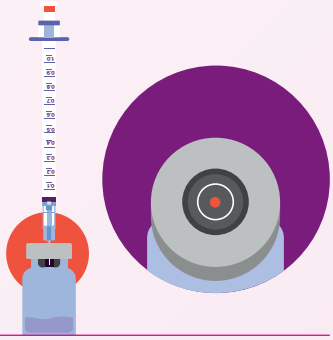


Step 7

- Take the **injection syringe**. Remove and discard the caps that cover both the top and bottom of the needle by pulling them straight up/down and off. **Remind caregivers about safe needle handling – be careful not to point it at anyone, including themselves**

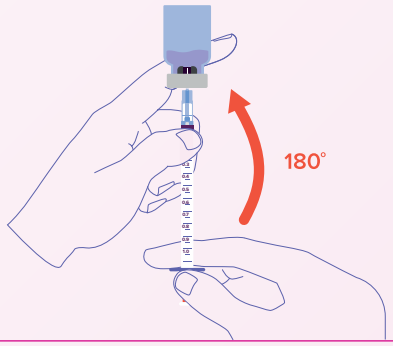
- Show caregivers how to completely insert the needle straight through the middle of the **vial stopper**

Explain how best not to touch the stopper sides or bend the injection needle.



Step 8

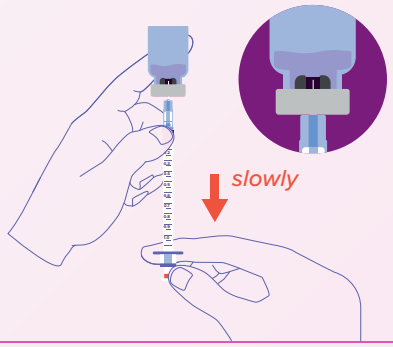
- **Securely and carefully** hold the **vial** and **syringe** together in place
- Turn them upside down so the **bottom of the vial** points at the ceiling



Show caregivers how to hold the vial using their index finger.

Step 9

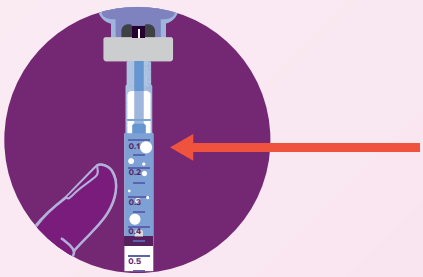
- Demonstrate how to keep the **needle tip** in the **medicine** while slowly pulling the plunger rod back to draw the **prescribed dose** into the syringe, avoiding air bubbles. Check that the prescribed dose is correct for the patient's body weight



Remind caregivers to continue to support the vial to avoid bending the needle.

Step 10

- Show caregivers how to closely examine the **injection syringe** for bubbles
- Demonstrate how to remove large air bubbles by gently **tapping** the base of the **syringe** and slowly **pushing** the plunger to get air bubbles back into the **vial**

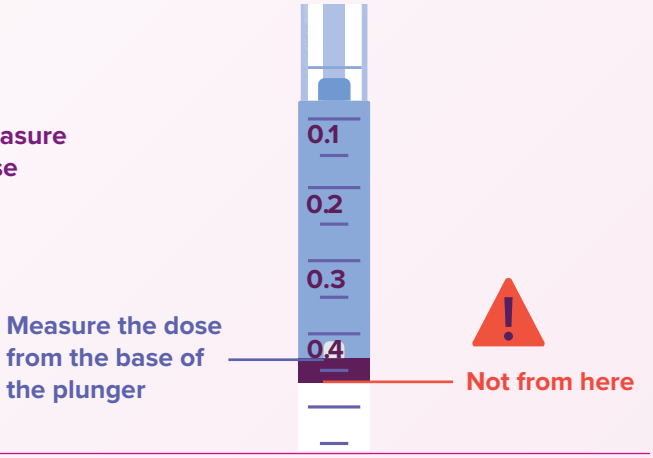


Eliminate any large bubbles. 1 or 2 small bubbles are acceptable.

Step 11

- Inform caregivers to repeat steps 9 and 10 until the **injection syringe** has the prescribed dose with no large bubbles. 1 or 2 small bubbles are acceptable
- Double-check to make sure the dose in the **injection syringe** matches the **prescribed dose**. It is not necessary to prime the needle

Explain how to measure the prescribed dose exactly as shown.



Step 12

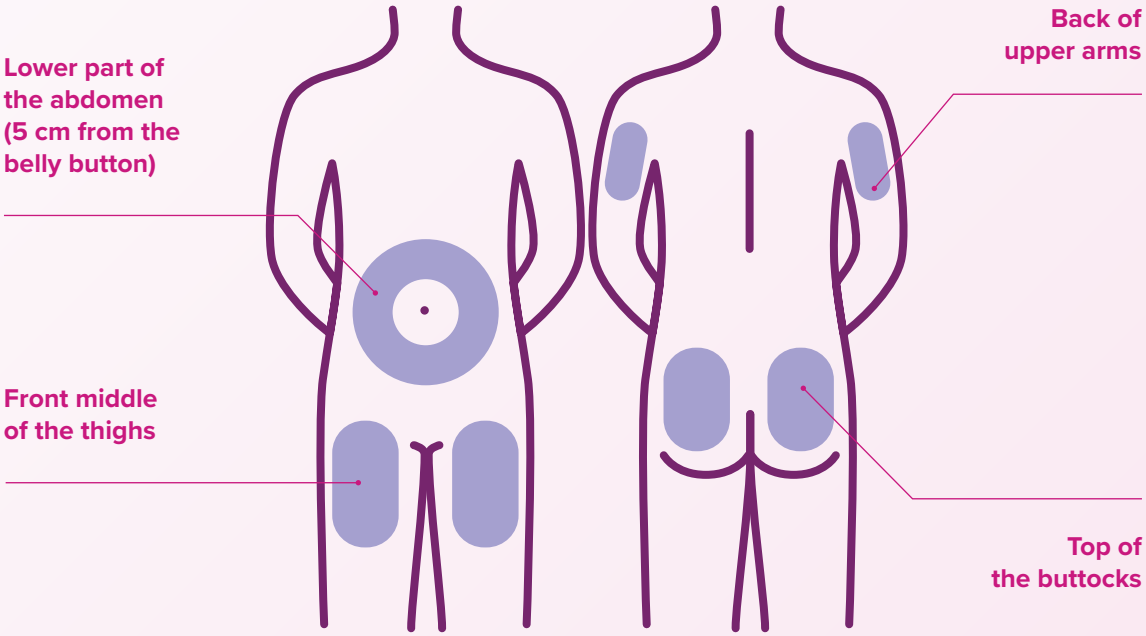
- Once caregivers have confirmed the prescribed dose is in the syringe, they should remove the **vial** by pulling it straight off the needle, and discard it in the nearby **sharps container**, even if there's leftover liquid

Next, it's important to review with caregivers how to prepare the injection site and administer VOXZOGO® while being careful not to contaminate the needle or drop the syringe.

Administration[1,2]

Step 13

There are 4 places caregivers can inject VOXZOGO®:



In young children, the recommended site for injections is thighs. Upper arms and buttocks can also be considered.

Remind caregivers not to inject into the same site two days in a row

Step 14

Clean the site

- Make sure the injection site is clean and dry. Do not touch the site before injecting.[3]

Inform caregivers not to inject through clothes.

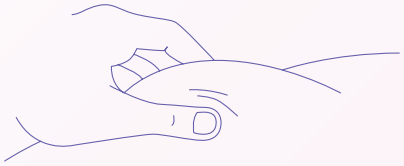
Caregivers should not inject VOXZOGO® into moles, birthmarks or skin that is sore, bruised, red, hard, or scarred.

How to administer VOXZOGO® in a few steps

Now that the VOXZOGO® syringe has been prepared, and they've selected and cleaned the injection site, encourage caregivers to check in with their child to make sure they're both ready and comfortable. Once everyone is comfortable, the caregiver will be ready to inject VOXZOGO®.

Step 15

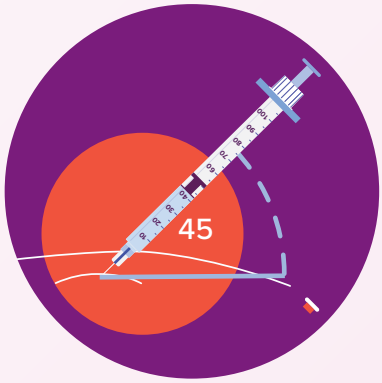
- Instruct caregivers to pinch the skin up around the injection site.



Step 16

- Show caregivers how to quickly insert the **injection needle** all the way into the skin at a 45-degree angle

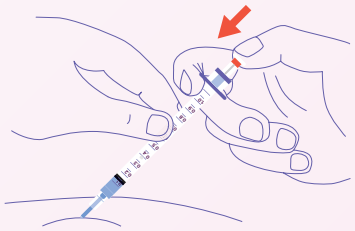
Note that this is different from the 90-degree angle used for many vaccinations.



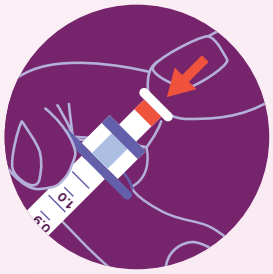
Step 17

- Release the pinch

Instruct caregivers how to use both hands: one to stabilise the syringe, the other to push the plunger.



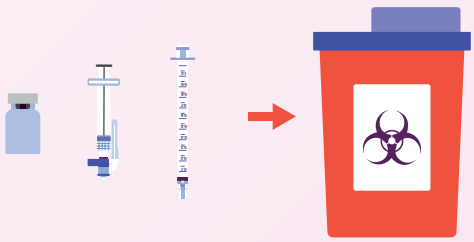
- **Slowly** push the plunger rod until all the medicine is injected and the syringe is empty. Caregivers will feel a slight resistance when the syringe is empty



- Continue press the plunger rod until the needle retracts into the syringe

Step 18

- Remind caregivers to dispose of the **vial, injection syringe** and **needle** in the **sharps container**



Step 19

Dizziness **Tiredness** **Feeling sick**

The most common adverse reactions in patients treated with VOXZOGO® were: injection site reactions (85%), vomiting (27%) and decreased blood pressure (13%)[1]. Please refer to the VOXZOGO® Product Information for further details.

- The caregiver should inspect the injection site – if there is a small amount of blood at the injection site, they can gently press a gauze pad on it for a few seconds or apply an adhesive bandage. **Caregivers should not rub the injection site**[2]
- The caregiver should look out for signs of low blood pressure, such as dizziness, tiredness, or feeling sick.[2] Let caregivers know to contact you if their child experiences any adverse reactions, while taking VOXZOGO®. Then instruct their child to lie down on their back and place cushions under their legs to raise them

▼ **This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at http://www.tga.gov.au/reporting-problems.**

Storage and Disposal

Storage and Disposal Information[1,2]

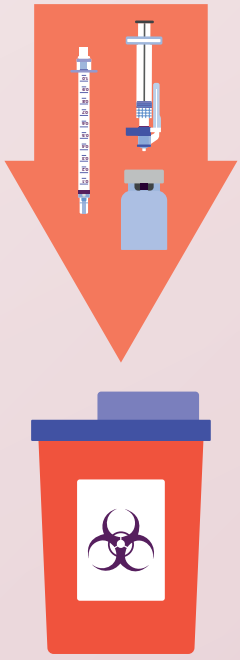
Storage

- Store VOXZOGO® in a refrigerator at 2-8°C. The VOXZOGO® vial and solvent syringe should be removed from the refrigerator and allowed to reach room temperature before preparing VOXZOGO® for injection
- Do not freeze
- Store in the original package to protect from light
- VOXZOGO® may be stored at room temperature (below 30°C) for up to 90 days
- Do not return VOXZOGO® to the refrigerator once it's at room temperature
- Do not use VOXZOGO® after the expiry date. Note that the expiry date refers to the last day of the month

Disposal

Do not throw away any medicines, vials, loose needles and syringes via household waste.

Dispose of used or expired vials, needles and injection syringes in a sharps container immediately after use.



Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Minimum Product Information

VOXZOGO (vosoritide)

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Indications: Voxzogo is indicated for the treatment of achondroplasia in paediatric patients whose epiphyses are not closed. The diagnosis of achondroplasia should be confirmed by appropriate genetic testing. **Contraindications:** Hypersensitivity to vosoritide or excipients. **Precautions:** Patients should be well hydrated at the time of injection to reduce the risk of a potential decrease in blood pressure and associated symptoms (dizziness, fatigue and/or nausea); use in elderly is not expected; no data are available for children under the age of <0.3 years; preferable to avoid use of Voxzogo during pregnancy; should not be used during breast-feeding; not to drive, cycle or use machines for at least 60 minutes after injection. **Adverse Effects:** The most common adverse reactions to Voxzogo were injection site reactions (injection site erythema, injection site reaction, injection site swelling, injection site urticaria, injection site pain, injection site bruising, injection site pruritus, injection site haemorrhage, injection site discolouration, and injection site induration), vomiting, and decreased blood pressure (both asymptomatic and symptomatic). Other adverse reactions in patients treated with Voxzogo included syncope, pre-syncope, dizziness, nausea, fatigue, increased alkaline phosphatase. **Dosage and Administration:** Treatment with Voxzogo should be initiated and directed by a physician appropriately qualified in the management of growth disorders or skeletal dysplasias. The volume of Voxzogo to be administered at the recommended dose is based on the patient's weight and the vosoritide concentration. Voxzogo treatment should be stopped upon confirmation of no further growth potential, indicated by a growth velocity of <1.5 cm/year and closure of epiphyses. If a dose is missed, it can be administered within 12 hours. If >12 hours have passed since the original dosing schedule, the missed dose should not be administered, and patients/caregivers should be advised to continue with the next scheduled dose the following day. Voxzogo is for subcutaneous single use in one patient only and must be administered within 3 hours of reconstitution. Patients and caregivers should be instructed to rotate sites for subcutaneous injections. Patients should be well hydrated at the time of injection; patients are recommended to eat a light snack and drink a glass of fluid about 30 minutes before injecting to reduce the signs and symptoms of potential decreases in blood pressure (dizziness, fatigue and/or nausea). If possible, Voxzogo should be injected at approximately the same time each day.

Before prescribing, please review Product Information available from BioMarin Pharmaceutical Australia Pty Ltd, 1800 387 876.

PBS Information: Authority required for achondroplasia confirmed by genetic testing. Refer to PBS Schedule for full authority information.

Date of preparation: 20 June 2024. Based on approved Product Information 5 June 2024.

References: 1. VOXZOGO® Product Information. **2.** VOXZOGO® Consumer Medicine Information. **3.** World Health Organization. WHO best practices for injections and related procedures toolkit, March 2010. Available at: https://www.who.int/publications/i/item/9789241599252 (Accessed on June 2025).

If you would like more information regarding achondroplasia, please scan the QR code or visit **https://www.biomarin.com.au**

BIOMARIN®

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