

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using VOXZOGO?

VOXZOGO contains the active ingredient vosoritide. VOXZOGO is used to treat a genetic condition called achondroplasia that affects growth of almost all bones in the body. The active ingredient in VOXZOGO works directly on the growth points of the bones to promote new bone growth. It is used in patients 2 years and older whose bones are still growing.

For more information, see Section [1. Why am I using VOXZOGO?](#) in the full CMI.

2. What should I know before I use VOXZOGO?

Do not use if you or your child have ever had an allergic reaction to VOXZOGO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have significant heart disease, blood pressure problems or any other medical conditions, take medicines that lower blood pressure or any other medicines, or are pregnant, plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use VOXZOGO?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How do I use VOXZOGO?

- In younger children, a caregiver should give the VOXZOGO injection as an injection under the skin. Do not inject yourself or your child with VOXZOGO until you have had proper training from a healthcare professional.
- Your doctor will choose the correct dose depending on your or your child's bodyweight. The doctor will tell you how much of the injection solution to inject.
- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

More instructions can be found in Section [4. How do I use VOXZOGO?](#) in the full CMI.

5. What should I know while using VOXZOGO?

Things you should do	<ul style="list-style-type: none"> • You or your child should eat a light snack and drink a glass of water, milk or juice about 30 minutes before the injection. This can reduce side effects such as dizziness, tiredness or nausea (feeling sick). • The injection should be given at around the same time each day.
Things you should not do	<ul style="list-style-type: none"> • Do not inject this medicine into moles, scars, birthmarks, or areas where the skin is tender, bruised, red, or hard.
Driving or using machines	<ul style="list-style-type: none"> • This medicine may cause you to feel dizzy, light-headed, tired or you may feel sick shortly after your injection. If this happens, you should not drive, ride a bicycle, do physical activities or use machines for around an hour after injection or until you feel better.
Looking after your medicine	<ul style="list-style-type: none"> • Follow the instructions in the carton on how to take care of your medicine properly. • Store in a refrigerator (2°C – 8°C). 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, but not beyond the expiry date. Do not return VOXZOGO to refrigerator after storage at room temperature.

For more information, see Section [5. What should I know while using VOXZOGO?](#) in the full CMI.

6. Are there any side effects?

The most common serious side effects are signs of low blood pressure, such as dizziness, feeling faint, light-headed or sick, and passing-out shortly after an injection. Other serious side effects are signs of sudden severe allergic reactions. The most common side effects include vomiting, tiredness and injection site reactions (e.g. redness, itching, inflammation, swelling, bruising, rash, hives, pain). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you or your child may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VOXZOGO[®]

Active ingredient: *vosoritide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VOXZOGO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VOXZOGO.**

Where to find information in this leaflet:

- [1. Why am I using VOXZOGO?](#)
- [2. What should I know before I use VOXZOGO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VOXZOGO?](#)
- [5. What should I know while using VOXZOGO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VOXZOGO?

VOXZOGO contains the active ingredient vosoritide.

VOXZOGO is a medicine used for the treatment of achondroplasia in patients 2 years and older whose bones are still growing.

Achondroplasia is a genetic condition that affects growth of almost all bones in the body including the skull, spine, arms and legs resulting in very short stature with a characteristic appearance.

The active substance in VOXZOGO works directly on the growth points of your bones to promote new bone growth.

2. What should I know before I use VOXZOGO?

Warnings

Do not use VOXZOGO if:

- You or your child are allergic to vosoritide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you or your child:

- have significant heart disease or blood pressure problems
- are taking or have recently taken medicines that lower blood pressure
- have any other medical conditions or take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The use of this medicine is not recommended during pregnancy and breastfeeding.

Blood pressure effects

VOXZOGO can lower blood pressure. As a result, you or your child may feel dizzy, nauseous, or tired. Blood pressure usually returns to normal within 90 minutes of VOXZOGO injection. If these effects occur and are severe, tell your doctor.

Drinking plenty of fluids at the time of injection may reduce the likelihood of these effects. It is recommended patients eat a light snack and drink a glass of fluid (e.g. water, milk or juice.) about 30 minutes before injection.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VOXZOGO and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VOXZOGO.

4. How do I use VOXZOGO?

How much to use

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. VOXZOGO is given as an injection slowly under the skin (subcutaneous injection).

Dose

- A caregiver should give the VOXZOGO injection to younger children. Do not inject yourself or your child with VOXZOGO until you have had proper training from a healthcare professional.
- Your doctor will choose the correct dose depending on your or your child's bodyweight. The doctor will tell you how much of the injection solution to inject. If you are not sure, ask your doctor or pharmacist.
- You or your child should eat a light snack and drink a glass of water, milk or juice about 30 minutes before the injection. This can reduce side effects such as dizziness, tiredness or nausea (feeling sick).

When to use VOXZOGO

- VOXZOGO should be used at around the same time each day.

How to use VOXZOGO

- The "Instructions for Use" (section 8 of this leaflet) shows you:
 - how to prepare and inject VOXZOGO and
 - how to discard VOXZOGO syringes properly after you use them
- Use VOXZOGO as soon as it has been made up as a solution. Once made, it must be used within 3 hours
- Inject VOXZOGO slowly under the skin (subcutaneous injection).
- It is recommended that you give the injection in a different place each day and do not use the same site 2 days in a row.

If you forget to use VOXZOGO

VOXZOGO should be used regularly at the same time each day. If you miss your dose at the usual time, the injection should still be given if it is within 12 hours of the scheduled time. If more than 12 hours have passed since the scheduled dose time, do not inject the missed dose. Wait until the next day and continue with the usual dose at the usual time.

If you use too much VOXZOGO

If you think that you have used too much VOXZOGO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VOXZOGO?

Things you should do

Call your doctor straight away if you or your child:

- start to feel dizzy or light-headed
- have recently taken medicines that lower blood pressure

Remind any doctor or pharmacist you visit that you or your child are using VOXZOGO.

Things you should not do

- Do not stop using this medicine suddenly. Always talk to your child's doctor before deciding to stop your child's treatment.
- Do not inject this medicine into moles, scars, birthmarks, or areas where the skin is tender, bruised, red, or hard.
- Do not use this medicine if the vial or syringe is damaged or you notice the solution is discoloured, cloudy, or if you can see particles.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VOXZOGO affects you.

VOXZOGO may cause you or your child to feel dizzy, light-headed, tired or sick shortly after the injection. If this happens, you should not drive, ride a bicycle, do physical activities or use machines for around an hour after injection or until you feel better. If your child is affected do not allow them to do physical activities, drive or ride a bicycle until they feel better.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package in order to protect from light.
- VOXZOGO may be stored at room temperature (below 30 °C) for up to 90 days, but not beyond the expiry date. Do not return VOXZOGO to refrigerator after storage at room temperature.
- Record on the carton the date you remove VOXZOGO from the refrigerator to store at room temperature.

Keep it where young children cannot reach it.

When to discard your medicine

Discard your medicine if it is past its expiry date (after "EXP" on packaging), if it has not been stored properly or if the pre-filled syringe is damaged or you notice the solution is discoloured, cloudy, or if you can see particles. The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

Use safe disposal procedures for syringes. Do not throw away any medicines via wastewater or household waste. If

you no longer need to use this medicine or it is out of date or has been stored incorrectly, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Vomiting • Tiredness • High levels of blood alkaline phosphatase (shown in blood tests) • Injection site reactions: <ul style="list-style-type: none"> ○ redness ○ itching ○ inflammation ○ swelling ○ bruising ○ rash ○ hives ○ pain. <p>Injection site reactions are usually minor and resolve on their own within a few hours.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Sudden severe allergic reactions, which include the following symptoms: <ul style="list-style-type: none"> ○ shortness of breath ○ wheezing or difficulty breathing ○ swelling of the face, lips, tongue or other parts of the body ○ rash, itching or hives on the skin. • Signs of low blood pressure, including: <ul style="list-style-type: none"> ○ nausea (feeling sick) ○ feeling faint or light-headed and passing out ○ prolonged dizziness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Make sure you keep all of your appointments with your doctor so they can monitor your condition. Some side effects can only be detected when your doctor does a blood test.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VOXZOGO contains

Active ingredient (main ingredient)	vosoritide
Other ingredients (inactive ingredients)	citric acid monohydrate sodium citrate dihydrate trehalose dihydrate mannitol methionine polysorbate 80 water for injections.

Do not take this medicine if you are allergic to any of these ingredients.

What VOXZOGO looks like

VOXZOGO powder and diluent for injection is provided as:

- a white to yellow powder for injection in a glass vial, and
- a clear and colourless diluent (water for injections) in a pre-filled syringe to dissolve the powder.

After dissolving the powder in the diluent, the solution is a clear, colourless to yellow liquid.

Each carton contains:

- 10 vials of VOXZOGO
- 10 pre-filled syringes of water for injections
- 10 individual single use needles
- 10 individual single use syringes

VOXZOGO is available with diluent in three strengths: 0.4 mg powder in a vial with white flip cap (AUST R 376616), 0.56 mg powder in a vial with magenta flip cap (AUST R 376617) and 1.2 mg powder in a vial with grey flip cap (AUST R 376618).

Who distributes VOXZOGO?

BioMarin Pharmaceutical Australia Pty Ltd
119 Willoughby Road
Crows Nest NSW 2065
Telephone (02) 8520 3255

For enquiries about VOXZOGO, contact medinfoasia@bmrn.com or call BioMarin on 1800 387 876.

To report adverse events, contact the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

This leaflet was prepared in July 2022.

8. INSTRUCTIONS FOR USE

BEFORE YOU START

Read this Instructions for use before you start using the VOXZOGO and each time you get a new prescription. There may be new information. Also, talk to your healthcare provider about your medical condition or your treatment.

Items provided to inject VOXZOGO (see Figure A)

Figure A

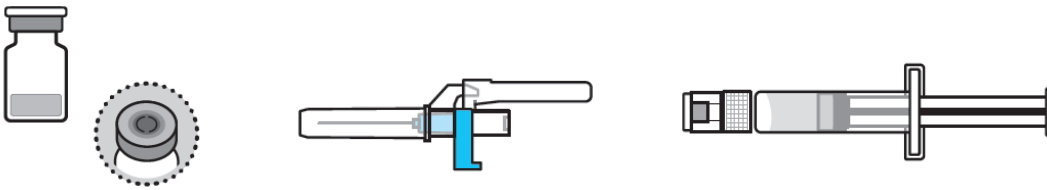
VOXZOGO vial

Diluent needle

Diluent syringe (Contains water for

(blue tab retracts needle)

injections for reconstitution of VOXZOGO)



Injections syringe



Items needed but *not* provided in the pack (see figure B)

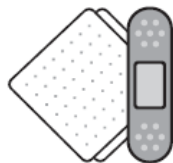
If you don't have these items, ask your pharmacist.

Figure B

Alcohol pads

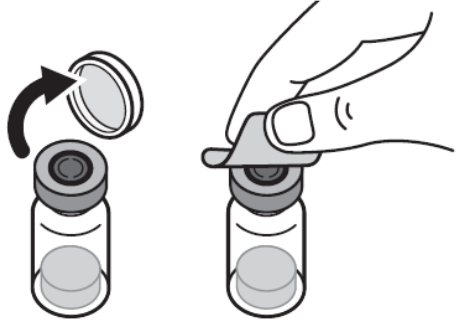
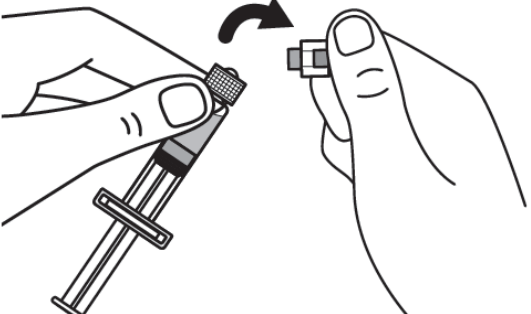
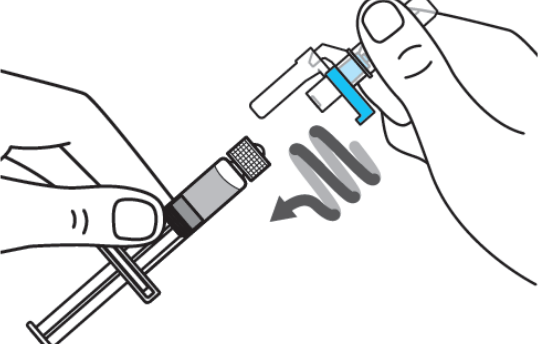
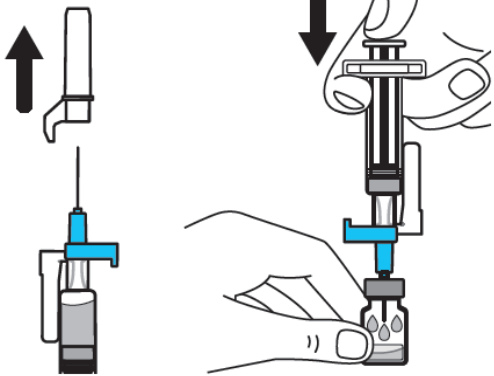
Sharps container

Gauze or bandage



PREPARING FOR INJECTION

Before you start, make sure you have a clean work surface and that you have washed your hands.

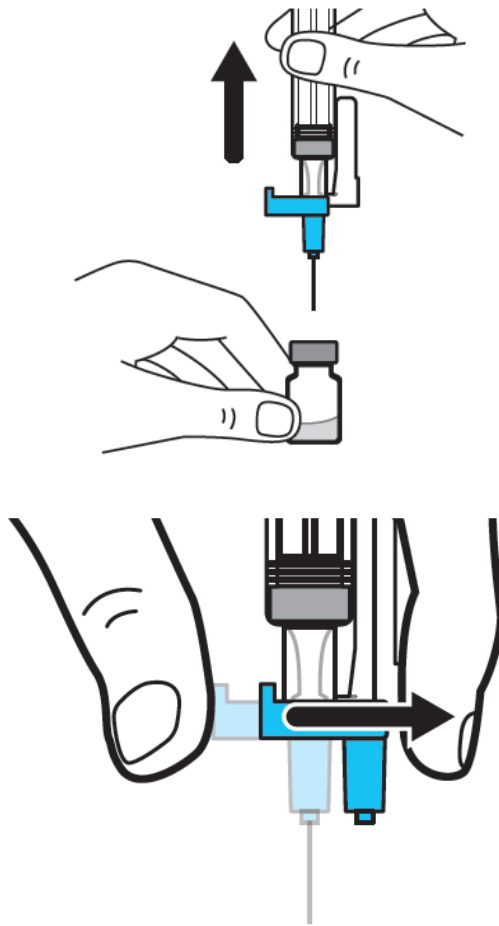
<p>Step 1: On a clean flat surface, flip off the vial cap and wipe the top with an alcohol pad.</p> <p>Do not touch the vial stopper with your fingers after wiping it with an alcohol pad.</p>	
<p>Step 2: Gently bend to snap off the cap from the diluent syringe.</p>	
<p>Step 3: Twist the diluent needle onto the diluent syringe until you can no longer twist it.</p>	
<p>Step 4: Pull off the needle cap and insert the needle into the vial through the middle of the vial stopper. Slowly push the plunger rod down to inject all of the liquid.</p> <p>Be careful not to push the blue tab until Step 5.</p>	

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 into a sharps container.

See step 18 and “How to throw away (dispose of) VOXZOGO.”

Do not use the diluent syringe to give the injection.

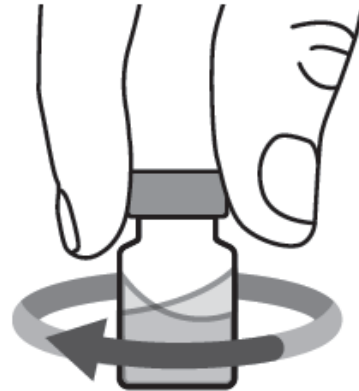
⚠ ATTENTION: Be careful not to touch the needle tip.



Step 6: Gently swirl the vial until the powder has completely dissolved and the solution is clear.

Do not shake.

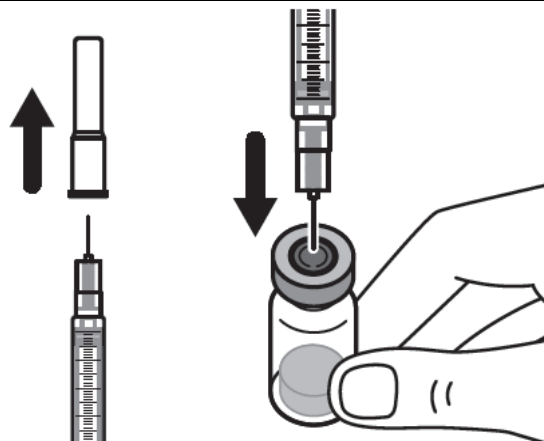
Make sure medicine is clear to yellow, not cloudy and is particle-free.

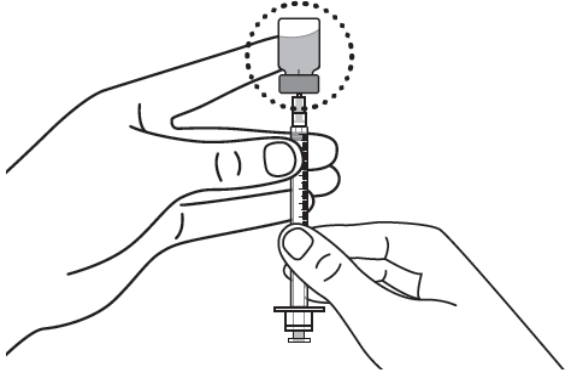
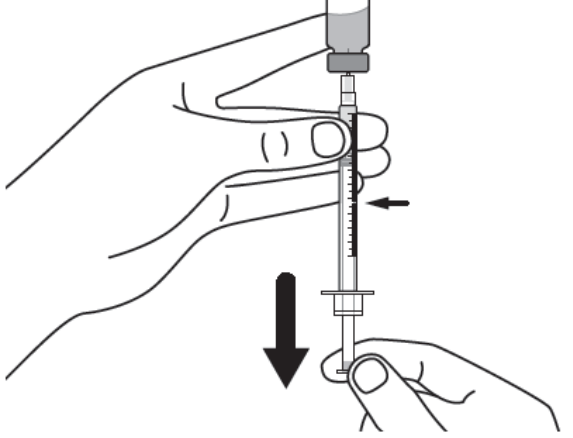
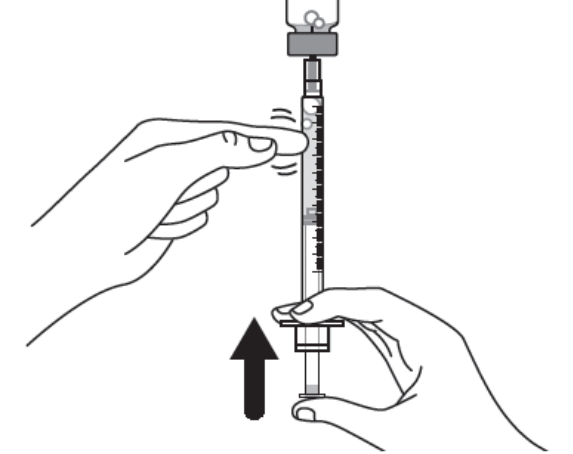
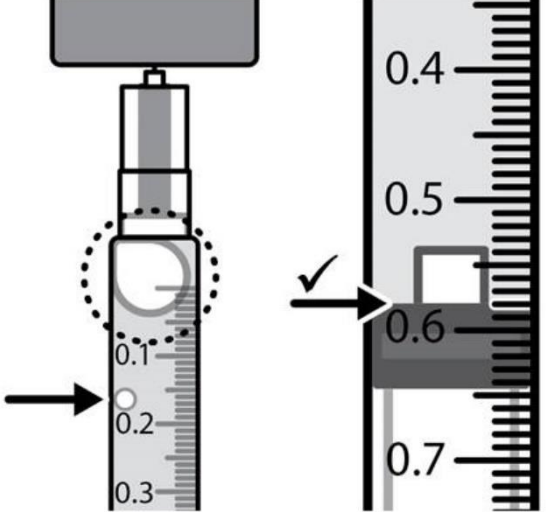


Step 7: Pull off the needle cap from the injection syringe and insert the needle into the vial straight through the middle of the vial stopper.

Be careful not to bend the needle.

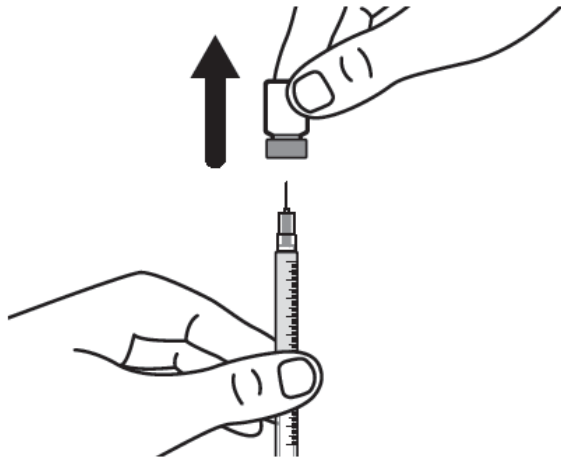
⚠ ATTENTION: Do not place the cap back on the needle.



<p>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.</p> <p>Be careful not to bend the needle.</p>	
<p>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.</p> <p>Check the prescription label for how much to draw up.</p> <p>⚠ ATTENTION: Draw up the prescribed dose.</p>	
<p>Step 10: Remove large air bubbles in the syringe by gently tapping the syringe. Then slowly push the bubbles back into the vial.</p>	
<p>Step 11: Repeat steps 9 and 10 until you have the correct prescribed dose in the syringe and no large bubbles.</p> <p>Make sure the dose in the syringe matches the prescribed dose. Measure from the base of the plunger as shown.</p> <p>⚠ ATTENTION: Remove any large bubbles. 1 or 2 small bubbles are acceptable.</p>	

Step 12: Make sure you have the prescribed dose in the syringe, then remove the vial and prepare to give the dose.

⚠ ATTENTION: Confirm amount matches the prescribed dose before removing vial.



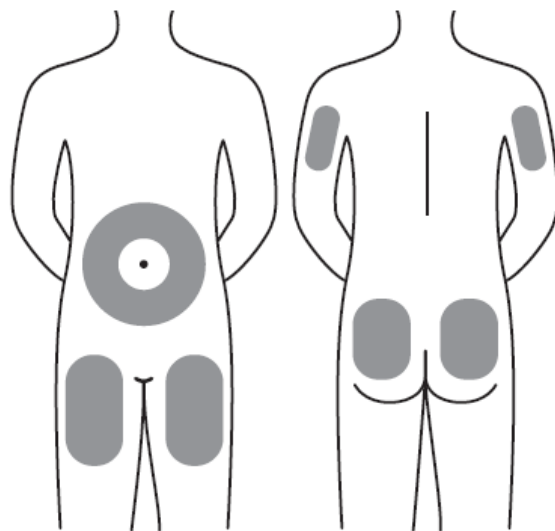
SELECTING AND PREPARING INJECTION SITE

Step 13: VOXZOGO should be injected into the fatty layer under the skin (subcutaneous) only.

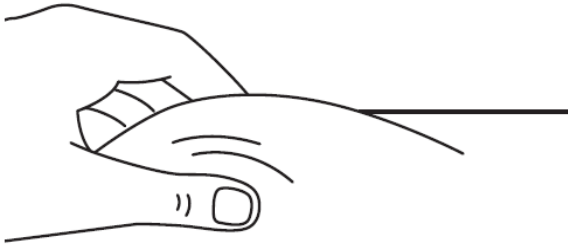
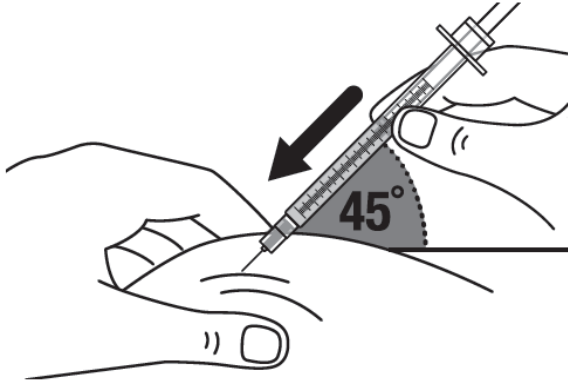
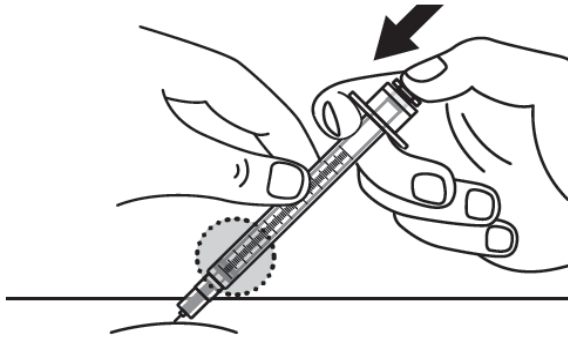
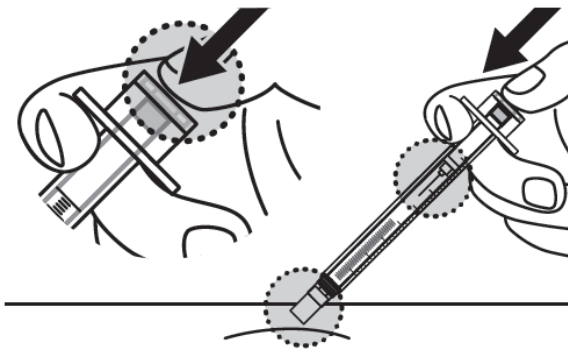
- Do not inject through clothes.
- Do not inject in the same site two times in a row.
- Do not inject into moles, birthmarks or skin that is sore, bruised, red, hard, or scarred.

The following sites are recommended for injection:

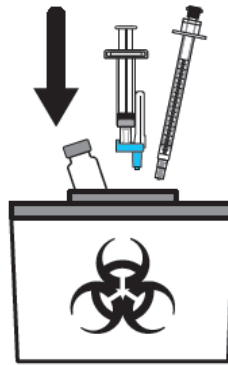
- **Back of upper arms** or
- **Thighs** or
- **Abdomen** (5 centimeters from belly button)
- **Buttocks**



GIVING VOXZOGO INJECTION

<p>Step 14: Pinch the skin up around the selected injection site.</p>	
<p>Step 15: Quickly insert the needle all the way into the skin at a 45-degree angle.</p>	
<p>Step 16: Release the pinch and slowly push the plunger rod all the way. Inject full dose.</p>	
<p>Step 17: Continue pressing the plunger rod until the needle retracts into the syringe.</p>	

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.



After injecting VOXZOGO

- Check the injection site. If there is a small amount of blood at the injection site, gently press a gauze pad on it for a few seconds or apply a bandage.
- **Do not** rub the injection site.
- Look out for signs of low blood pressure, such as dizziness, tiredness, or feeling sick. If you have these symptoms call your doctor or healthcare provider, then lie down on your back and place cushions under your legs to raise them.

How to throw away (dispose of) VOXZOGO

Put your used or expired vials, needles and syringes in a sharps disposal container right away after use.

If you do not have a 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 labelled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Do not throw away any medicines, vials, loose needles and syringes via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.