



**Annika, 14 years old,**  
living with achondroplasia,  
receiving VOXZOGO as  
part of a clinical trial

# VOXZOGO AT A GLANCE

VOXZOGO is a **once-daily injection given at home** to increase linear growth in children with achondroplasia aged 5 years and up whose growth plates are still open. A healthcare provider will show you how to administer VOXZOGO before you use it for the first time.

**VOXZOGO**<sup>™</sup>  
(vosoritide) for injection

## What is VOXZOGO used for?

- VOXZOGO is a prescription medicine used to increase linear growth in children with achondroplasia who are 5 years of age and older with open growth plates (epiphyses).
- It is not known if VOXZOGO is safe and effective in children with achondroplasia under 5 years of age.
- VOXZOGO is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

## **IMPORTANT SAFETY INFORMATION**

### What is the most important safety information about VOXZOGO?

- VOXZOGO may cause serious side effects including a temporary decrease in blood pressure in some patients. To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, feeling tired, or nausea), patients should eat a meal and drink 8 to 10 ounces of fluid within 1 hour before receiving VOXZOGO.

Please see **Important Safety Information** throughout as well as the full [Prescribing Information](#) and [Patient Information](#).

# VOXZOGO helps improve growth rates in children aged 5 years and up with achondroplasia

A clinical trial focused on how VOXZOGO™ (vosoritide) affects growth rates, or **annualized growth velocity (AGV)**, a measure of bone growth over 1 year. When the clinical trial began, it had a total of **121 participants** between the ages of 5 and 15 years receiving either VOXZOGO (N=60) or placebo (N=61).

## VOXZOGO improved growth rates after 1 year compared to placebo



Children receiving **VOXZOGO**, on average, had an increase in AGV from **1.68** in/yr before starting VOXZOGO to **2.23** in/yr after 1 year on VOXZOGO



Children receiving **placebo**, on average, had a change in AGV from **1.60** in/yr before starting placebo to **1.53** in/yr after 1 year on placebo

*Growth rates vary by age, sex, and individual. Individual growth rates with VOXZOGO may be different and may change over time.*

### How does VOXZOGO work?

The balance between fibroblast growth receptor 3 (FGFR3) and C-type natriuretic peptide (CNP) signaling pathways is important for bone growth. FGFR3 slows bone growth while CNP promotes bone growth. In achondroplasia, overactive FGFR3 signaling leads to impaired bone growth throughout the body.

**VOXZOGO increases CNP signaling to target overactive FGFR3 signaling in achondroplasia.**

### What are the most common side effects of VOXZOGO?

- The most common side effects of VOXZOGO include injection site reactions (including redness, itching, swelling, bruising, rash, hives, and injection site pain), vomiting, joint pain, decreased blood pressure, and stomach ache. These are not all the possible side effects of VOXZOGO. Ask your healthcare provider for medical advice about side effects, and about any side effects that bother the patient or that do not go away.

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# What are the side effects of VOXZOGO?

This chart shows the number of patients that experienced the most common side effects on VOXZOGO™ (vosoritide) compared to placebo.

Side effects occurring in over 10% of VOXZOGO patients*		
SIDE EFFECTS	PLACEBO (N=61)	VOXZOGO (N=60)
Injection site reddening (erythema) <sup>†</sup>	42 (69%)	45 (75%)
Injection site swelling <sup>†</sup>	22 (36%)	37 (62%)
Vomiting	12 (20%)	16 (27%)
Injection site hives (urticaria) <sup>†</sup>	6 (10%)	15 (25%)
Joint pain (arthralgia)	4 (7%)	9 (15%)
Decreased blood pressure	3 (5%)	8 (13%)
Stomach ache (gastroenteritis) <sup>‡</sup>	5 (8%)	8 (13%)

\*Includes adverse reactions occurring in over 10% of VOXZOGO patients and more frequently in the VOXZOGO arm with a risk difference of  $\geq 5\%$  (ie, difference of  $>2$  subjects) between treatment arms.

<sup>†</sup>Injection site reactions occurring more frequently in patients treated with VOXZOGO than those treated with placebo.

<sup>‡</sup>Includes the preferred terms: gastroenteritis and gastroenteritis, viral.

VOXZOGO may cause serious side effects including a temporary decrease in blood pressure in some patients. To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, feeling tired, or nausea), patients should be well fed and hydrated in the hour before receiving VOXZOGO.

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Sign up to learn more at [VOXZOGO.com](https://www.voxzogo.com)

## How is VOXZOGO taken?

- VOXZOGO is taken daily as an injection given under the skin, administered by a caregiver after a healthcare provider determines the caregiver is able to administer VOXZOGO. Do not try to inject VOXZOGO until you have been shown the right way by your healthcare provider. VOXZOGO is supplied with Instructions for Use that describe the steps for preparing, injecting, and disposing VOXZOGO. Caregivers should review the Instructions for Use for guidance and any time they receive a refill of VOXZOGO in case any changes have been made.

Please see Important Safety Information throughout as well as the full [Prescribing Information](#) and [Patient Information](#).

# Important Safety Information

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- Inject VOXZOGO 1 time every day, at about the same time each day. If a dose of VOXZOGO is missed, it can be given within 12 hours from the missed dose. After 12 hours, skip the missed dose and administer the next daily dose as usual.
- The dose of VOXZOGO is based on body weight. Your healthcare provider will adjust the dose based on changes in weight following regular check-ups.
- Your healthcare provider will monitor the patient's growth and tell you when to stop taking VOXZOGO if they determine the patient is no longer able to grow. Stop administering VOXZOGO if instructed by your healthcare provider.

## **What should you tell the doctor before or during taking VOXZOGO?**

- Tell your doctor about all of the patient's medical conditions including
  - If the patient has heart disease (cardiac or vascular disease), or if the patient is on blood pressure medicine (anti-hypertensive medicine).
  - If the patient has kidney problems or renal impairment.
  - If the patient is pregnant or plans to become pregnant. It is not known if VOXZOGO will harm the unborn baby.
  - If the patient is breastfeeding or plans to breastfeed. It is not known if VOXZOGO passes into breast milk.
- Tell your doctor about all of the medicines the patient takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You may report side effects to BioMarin at **1-866-906-6100**. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call **1-800-FDA-1088**.

**Please see additional safety information in the full [Prescribing Information](#) and [Patient Information](#).**

**Talk to your doctor to get started with VOXZOGO**

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**BIOMARIN®**