BioMarin Rare Connections™

Patient Enrollment Form for VOXZOGO™ (vosoritide) for injection

Fax completed form with prescriber's signature to **1.833.869.0323**
Phone: **1.833.VOXZOGO** (1.833.869.9646); hours: M–F, 6 AM–5 PM (PT)
Email: **support@biomarin-rareconnections.com**

VOXZOGO™ (vosoritide) for injection

Patient is ☐ New to VOXZOGO ☐ Renewing prescription ☐ CoPay Assistance Only

PATIENT

Patient's Last Name		Patient's First Name	Middle Initial
Date of Birth	Gender ☐ Male ☐ Female ☐ Other	Parent's/Guardian's Name (if applicable)	
Street Address		Suite/Floor/Apt	
City		State	ZIP Code
Shipping Address (if different than home address); no PO Box		Suite/Floor/Apt	
City		State	ZIP Code
Preferred Method of Contact (please specify) ☐ Cell Phone ☐ Home Phone ☐ Alternative Phone			
☐ Email		☐ I authorize BioMarin RareConnections to leave a message if I am not available	
Language Preferred: ☐ English ☐ Spanish ☐ Other language (please specify)			
Alternate Contact Name		Relationship to Patient	
Phone	Email	☐ I authorize BioMarin RareConnections to leave a message with Alternate Contact	

INSURANCE

Please complete the following or attach copies of all medical and prescription insurance cards

☐ Insurance card copies attached ☐ Patient has no insurance

Primary Insurance Name		Secondary Insurance Name	
Insurance Phone Number		Insurance Phone Number	
Subscriber		Subscriber	
Relationship to Patient		Relationship to Patient	
Member ID	Group ID	Member ID	Group ID
Employer		Employer	

PRESCRIBER

Prescriber's First Name	Prescriber's Last Name	☐ MD ☐ DO ☐ PA-C ☐ NP		
Prescriber's Specialty: ☐ Pediatrician ☐ Pediatric endocrinologist ☐ Geneticist ☐ Other specialty (please specify)				
Office/Clinic/Institution Name				
Street Address		City	State	ZIP Code
Prescriber Email		Office Contact's Name		
Office Contact's Phone Number	Office Contact's Fax Number	Office Contact's Email		
Preferred Method of Contact (please specify) ☐ Office Contact's Phone ☐ Office Contact's Fax ☐ Office Contact's Email				
State License Number		Medicaid Number		
NPI Number		Tax ID		
Will prescriber oversee patient's follow-up care? ☐ Yes ☐ No If no, please specify name of physician who will manage and maintain patient (eg, ongoing visits, measurements, etc.)				State

Patient's Full Name	Date of Birth

CLINICAL INFORMATION

Diagnosis and clinical information ☐ Q77.4 Achondroplasia ☐ Other diagnosis (please specify) _____

ICD-10-CM Q77.4 is used for both achondroplasia and hypochondroplasia; VOXZOGO™ (vosoritide) is only indicated for increasing linear growth in pediatric patients with achondroplasia 5 years of age and older whose growth plates are open. If patient has hypochondroplasia, select "Other diagnosis" and indicate.

Patient height (cm) Patient weight (kg) Date weight taken

Patient Drug and Food Allergies
☐ NKDA ☐ Yes (please list)

Is patient taking concurrent medication?
☐ No ☐ Yes (please list)

PRESCRIPTION

Inject subcutaneous daily dose based on the patient's weight and the VOXZOGO concentration table below

Body Weight (kg)	**VOXZOGO 0.4 mg/vial** NDC: 68135-0082-36 10 doses **Diluent** (Sterile Water for Injection, USP): **0.5 mL** **Concentration: 0.8 mg/mL**	**VOXZOGO 0.56 mg/vial** NDC: 68135-0119-66 10 doses **Diluent** (Sterile Water for Injection, USP): **0.7 mL** **Concentration: 0.8 mg/mL**	**VOXZOGO 1.2 mg/vial** NDC: 68135-0181-93 10 doses **Diluent** (Sterile Water for Injection, USP): **0.6 mL** **Concentration: 2 mg/mL**
	Daily injection volume (mL)		
10-11	**0.3 mL (0.24 mg)**		
12-16		**0.35 mL (0.28 mg)**	
17-21		**0.4 mL (0.32 mg)**	
22-32		**0.5 mL (0.4 mg)**	
33-43			**0.25 mL (0.5 mg)**
44-59			**0.3 mL (0.6 mg)**
60-89			**0.35 mL (0.7 mg)**
≥90			**0.4 mL (0.8 mg)**

✔	Vial Strength	Directions for Use	Quantity to Dispense	Refills
☐	VOXZOGO 0.4 mg/vial (0.8 mg/mL) Kit	Reconstitute vial with 0.5 mL of sterile water and inject _____ mL subcutaneously once daily	☐ 1-month supply (3 kits) ☐ 3-month supply (9 kits) Other _____	_____#
☐	VOXZOGO 0.56 mg/vial (0.8 mg/mL) Kit	Reconstitute vial with 0.7 mL of sterile water and inject _____ mL subcutaneously once daily		
☐	VOXZOGO 1.2 mg/vial (2 mg/mL) Kit	Reconstitute vial with 0.6 mL of sterile water and inject _____ mL subcutaneously once daily		

Each kit contains 10 vials of VOXZOGO, 10 single-dose prefilled diluent syringes (Sterile Water for Injection, USP), 10 needles, and 10 syringes.
Syringes and needles are custom and not interchangeable.

Ancillary Supplies—Specialty Pharmacy will confirm patient need for all selected ancillary supplies prior to each shipment

☐ Sharps container ☐ Alcohol wipes ☐ Gauze ☐ Adhesive bandages ☐ Gloves (latex free)

Special Delivery Instructions

Prescriber Declaration: I understand and agree that, as the prescriber, I will comply with my state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me, as the prescriber. I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed VOXZOGO based on my professional judgment of medical necessity. I authorize BioMarin Pharmaceutical Inc., its affiliates, agents and contractors (collectively, "BioMarin") to act on my behalf for the limited purposed of transmitting this prescription by any means under applicable law to the appropriate pharmacy designated by the above-name patient utilizing their benefit plan. I also authorize the BioMarin RareConnections™ program to perform any steps necessary to secure reimbursement for VOXZOGO, including but not limited to insurance verification and case assessment. I understand that BioMarin or BioMarin RareConnections may need additional information, and I agree to provide it as needed for the purposes of securing reimbursement.

I agree and attest that, should my patient receive free drug from BioMarin, I will not submit a claim to or seek payment from the patient or any third-party payer (e.g., Medicaid, Medicare, private insurance, etc.) for payment/reimbursement for any free product(s) provided by BioMarin. I agree and understand that any free product provided by BioMarin may not be sold, traded, bartered, transferred, or returned for credit and will only be used for the patient named above on this form.

Prescriber's Signature. Please make a selection

Prescriber's Signature/Dispense as Written (no stamps or initials)	Date	Prescriber's Signature/Substitution Permitted (no stamps or initials)	Date

Indication and Important Safety Information

VOXZOGO™ (vosoritide) is indicated to increase linear growth in pediatric patients with achondroplasia 5 years of age and older with open growth plates.

- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Warnings and Precautions for Risk of Low Blood Pressure

Transient decreases in blood pressure were observed in clinical studies. Patients with significant cardiac or vascular disease and patients on anti-hypertensive medicinal products were excluded from participation in VOXZOGO clinical trials. To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, fatigue, and/or nausea), patients should be well hydrated, have adequate food intake, and drink approximately 8-10 ounces of fluid in the hour prior to VOXZOGO administration.

Eight (13%) of 60 patients treated with VOXZOGO had a total of 11 events of transient decrease in blood pressure, compared to 3 (5%) of 61 patients on placebo, over a 52-week treatment period. The median time to onset from injection was 31 (18 to 120) minutes, with resolution within 31 (5 to 90) minutes in VOXZOGO-treated subjects. Two out of 60 (3%) VOXZOGO-treated patients each had one symptomatic episode of decreased blood pressure with vomiting and/or dizziness compared to 0 of 61 (0%) patients on placebo.

Adverse Reactions:

Adverse reactions that occurred in ≥5% of patients treated with VOXZOGO and at a rate greater than that of placebo in the phase 3 study are injection site reactions (including erythema, swelling, urticaria, pain, bruising, pruritus, hemorrhage, discoloration, and induration), vomiting, arthralgia, decrease in blood pressure, gastroenteritis, diarrhea, dizziness, ear pain, influenza, fatigue, seasonal allergy, and dry skin.

Injection site reactions: Injection site reactions occurred in 51 (85%) subjects receiving VOXZOGO and 50 (82%) subjects receiving placebo over a 52-week period of treatment. Patients receiving VOXZOGO experienced a total of 6983 events of injection site reactions, while patients receiving placebo experienced a total of 1776 events of injection site reactions, over a 52-week period, representing 120.4 events per patient/year exposure and 29.2 events per patient/year exposure, respectively. Two patients in the VOXZOGO arm discontinued treatment due to adverse events of pain and anxiety with injections.

Administration and Monitoring:

VOXZOGO is administered as a daily subcutaneous injection. Prior to use, instruct caregivers on proper preparation and administration of VOXZOGO, and ensure caregivers have demonstrated the ability to perform a subcutaneous injection.

Monitor and assess patient body weight, growth, and physical development regularly every 3-6 months. Adjust dosage according to the patient's actual body weight. Permanently discontinue treatment with VOXZOGO upon confirmation of no further growth potential, indicated by closure of epiphyses.

Special Populations:

- Safety and effectiveness of VOXZOGO in pediatric patients with achondroplasia below the age of 5 years have not been established.
- There are no available data on the use of VOXZOGO in pregnant women, or data on the presence of VOXZOGO in human milk, the effects on the breastfed infant, or the effects on milk production.
- The influence of renal impairment on the pharmacokinetics of VOXZOGO has not been evaluated. No dosage adjustment is needed for patients with eGFR ≥ 60 mL/min/1.73 m^2. VOXZOGO is not recommended for patients with eGFR < 60 mL/min/1.73 m^2.

You may report side effects to the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**. You may also report side effects to BioMarin at **1-866-906-6100**.

Please see additional safety information in the full Prescribing Information.

BIOMARIN®

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