VOXZOGO®▼
(vosoritide) for injection

A treatment designed to target overactive FGFR3 signalling and promote endochondral bone growth

Intended for HCPs only.

SINGLE DOSE VOLUMES BY BODY WEIGHT[2]

Body weight (kg)	VOXZOGO® 0.4 mg diluent (water for injections): 0.5 mL concentration: 0.8 mg/mL	VOXZOGO® 0.56 mg diluent (water for injections): 0.7 mL concentration: 0.8 mg/mL	VOXZOGO® 1.2 mg diluent (water for injections): 0.6 mL concentration: 2 mg/mL
	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**

VOXZOGO® is PBS LISTED

PBS codes for VOXZOGO®[1]

	Initiation	Continuation
VOXZOGO® 0.4 mg powder and diluent for injection	123456A	123456D
VOXZOGO® 0.56 mg powder and diluent for injection	123456B	123456E
VOXZOGO® 1.2 mg powder and diluent for injection	123456C	123456F

- ☐ **Genetic test result for achondroplasia documented in medical records**
- ☐ **No evidence of growth plate closure demonstrated by at least one of following:**
  - **I.** Bilateral lower extremity X-rays (proximal tibia, distal femur) documented in medical records
    - taken within last 2 years for pre-pubertal patients
    - taken within last 6 months if puberty commenced
  - **II.** Annual growth velocity >1.5cm/year assessed over a period of at least 6 months

Applications for authorisation may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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. Schedule of Pharmaceutical Benefits (PBS). (www.pbs.gov.au). **2.** VOXZOGO® (vosoritide). Approved Product Information. 5 June 2024.

BIOMARIN®

BioMarin Pharmaceutical Australia Pty Ltd
119 Willoughby Rd, Crows Nest, NSW 2065
Ph +61 2 9967 8662 Medical Information 1800 387 876

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