Date: 25 May 2023

Voxzogo® (vosoritide): change to administration syringe and needle leading to product administration in Units (U) instead of mL

Dear Healthcare Professional,

BioMarin International Limited in agreement with the European Medicines Agency and <National competent authority> would like to inform you of the following:

Summary

- **From July 2023, Voxzogo co-packs will contain new solvent needles and new administration syringes due to supply chain reasons.**
- **The new solvent needle has an alternative safety mechanism with an activated safety shield cover (see Table 1 below).**
- **The new administration syringe has Units (U) graduation markings(typically used for insulin products and sometimes referred to as Insulin Units) instead of mL graduation markings (see Table 1 below).**
- **It is important that you explain to your patient or the caregiver the recommended dose to be delivered with the new syringe, as the units of measure are not 1:1. For example, 0.1 mL is equivalent to 10 U. Please see Table 2 below for the conversion of single dose volumes from mL to U.**
- **There are no changes to the Voxzogo dosage or volume. Recommendations for use remain unchanged.**
- **The product information has been amended to reflect the use of new needles and syringes.**

Table 1 Current and new solvent needle and administration syringe

	Current component	**New component**
Solvent needle: safety shield		
Administration syringe: graduation markings		

Table 2 Single dose volume calculation in mL and Units

Body weight (kg)	**Vosoritide 0.4 mg solvent (water for injections): 0.5 mL concentration: 0.8 mg/mL**		**Vosoritide 0.56 mg solvent (water for injections): 0.7 mL concentration: 0.8 mg/mL**		**Vosoritide 1.2 mg solvent (water for injections): 0.6 mL concentration: 2 mg/mL**	
	Daily injection volume					
	mL	Units	mL	Units	mL	Units
10-11	0.30 mL	30 U				
12-16			0.35 mL	35 U		
17-21			0.40 mL	40 U		
22-32			0.50 mL	50 U		
33-43					0.25 mL	25 U
44-59					0.30 mL	30 U
60-89					0.35 mL	35 U
≥ 90					0.40 mL	40 U

Background

Voxzogo (vosoritide) 0.4 mg/0.56 mg/1.2 mg powder and solvent for solution for injection is indicated for the treatment of achondroplasia in patients 2 years of age and older whose epiphyses are not closed. It is supplied as a lyophilized powder in single dose vials along with sterile water for injection as a solvent in pre-filled syringes. The Voxzogo co-pack also includes two ancillaries, a solvent transfer needle for product reconstitution and an administration syringe.

From July 2023, Voxzogo co-packs will contain different solvent needles and administration syringes due to supply chain reasons. It is important that healthcare professionals inform the caregivers and patients about this change to ensure the correct dose administration of Voxzogo.

Call for reporting

Reporting suspected adverse drug reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system: <Insert local contact information>.

When reporting a suspected adverse drug reaction, please provide the product name and the specific batch number.

Voxzogo is labelled with the black triangle, this means that it is being monitored even more intensively than other medicines. This is because there is limited data on its long-term use.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

You also may contact our medical information department at medinfoeu@bmrn.com if you have any questions about the information contained in this letter or the safe and effective use of Voxzogo.

Yours sincerely,

BioMarin signature

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Voxzogo / Vosoritide
Marketing authorisation holder(s)	BioMarin International Limited
Safety concern and purpose of the communication	Change to administration syringe and needle leading to product administration in Units (U) instead of mL
DHPC recipients	**DHCP recipients**: prescribing physicians (e. g. Paediatric endocrinologists, geneticists, general paediatricians), site nurses and home nurses, hospital/retail pharmacists and other HCPs involved in prescription, dispensing and administration and vendors in countries with Patient Support Programs - PSP. The NCAs should further decide which specialists are relevant to receive the DHPC based on the national clinical practice.
Member States where the DHPC will be distributed	**Member States where the DHPC will be distributed:** Germany, France, Croatia, Belgium, Bulgaria, Italy, Estonia, Czech Republic, Spain, Austria, Greece, Slovenia, Slovakia, Luxemburg and all other Member States where Voxzogo is marketed.

Timetable *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by PRAC	25 May
DHPC and communication plan (in English) agreed by CHMP/CMDh	25 May
Submission of translated DHPCs to the national competent authorities for review	9 June
Agreement of translations by national competent authorities	Proposed 15 June (~1 week after the translation dependent upon respective NCA)
Dissemination of DHPC	Shortly ahead of the launch of the product in the respective MS