

PATIENT INFORMATION
VOXZOGO (vox zoe' goe)
(vosoritide)
for injection, for subcutaneous use

What is VOXZOGO?

VOXZOGO is a prescription medicine used to increase linear growth in children with achondroplasia who are 5 years of age and older with open bone growth plates (epiphyses).

It is not known if VOXZOGO is safe and effective in children with achondroplasia under 5 years of age.

Before you give your child VOXZOGO, tell your child's healthcare provider about all your child's medical conditions, including if they:

- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if VOXZOGO will harm your child's unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VOXZOGO passes into your child's breast milk. Talk to your child's healthcare provider about the best way to feed your child's baby if your child takes VOXZOGO.

Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines your child takes. Keep a list of them to show your child's healthcare provider and pharmacist when your child gets a new medicine.

How should I give VOXZOGO?

- See the detailed **Instructions for Use** that comes with this Patient Information leaflet for instructions about the right way to store, prepare, and give VOXZOGO injections at home.
- VOXZOGO is given as an injection under the skin (subcutaneous or SC). Inject VOXZOGO 1 time every day, at about the same time each day.
- If your child's healthcare provider decides a caregiver can give the injections of VOXZOGO at home, your child's caregiver should receive training on the right way to prepare and inject VOXZOGO. Do not try to inject VOXZOGO until you have been shown the right way by your child's healthcare provider or nurse.
- Your child's healthcare provider will tell you how often you should give VOXZOGO. If your child misses a dose of VOXZOGO, it can be given within 12 hours of the scheduled time of injection. If more than 12 hours have passed, do not give the missed dose. Give the next daily dose according to your child's usual schedule.
- Your child should eat a meal and drink about 8 to 10 ounces of fluid within 1 hour before injection.
- In case you are not sure when to inject VOXZOGO, call your child's healthcare provider or pharmacist. Do not give VOXZOGO more often than as directed by your child's healthcare provider.
- Your child's dose of VOXZOGO depends on his or her body weight. Your child's healthcare provider will tell you which strength of VOXZOGO to use and how much to give your child.
- Your child's healthcare provider will monitor your child's growth and instruct you on when your child should stop VOXZOGO if they determine that your child is no longer able to grow. Stop giving VOXZOGO to your child if instructed by your child's healthcare provider.

What are the possible side effects of VOXZOGO?

VOXZOGO may cause serious side effects, including:

- **risk of low blood pressure.** VOXZOGO may temporarily lower blood pressure in some people. To help reduce the risk of low blood pressure and its symptoms (dizziness, feeling tired, or nausea), your child should eat a meal and drink about 8 to 10 ounces of fluid within 1 hour before receiving VOXZOGO.

The most common side effects of VOXZOGO include:

- injection site reactions (redness, itching, swelling, bruising, rash, hives, pain)
- vomiting
- joint pain
- decreased blood pressure

- stomach ache

These are not all the possible side effects of VOXZOGO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VOXZOGO?

- Store the VOXZOGO vial and prefilled diluent syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- You may store VOXZOGO (before mixing) at room temperature between 68°F to 77°F (20°C to 25°C) for 90 days.
- Record the date you started storing VOXZOGO at room temperature on the carton to keep track of the 90 days.
- **Do not** return VOXZOGO to the refrigerator after it has been stored at room temperature. Throw VOXZOGO away if unused within 90 days of storing at room temperature.
- Do not use VOXZOGO past the expiration date.
- Do not freeze VOXZOGO.
- Store VOXZOGO out of direct sunlight.

Keep VOXZOGO and all medicines out of the reach of children.

General information about the safe and effective use of VOXZOGO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VOXZOGO for a condition for which it was not prescribed.

Do not give VOXZOGO to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about VOXZOGO that is written for health professionals.

What are the ingredients in VOXZOGO?

Active ingredient: vosoritide

Inactive ingredients: trehalose dihydrate, mannitol, sodium citrate dihydrate, methionine, citric acid monohydrate, and polysorbate 80



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For more information, go to www.VOXZOGO.com or call 1-877-695-8826.

This Patient Information has been approved by the U.S. Food and Drug Administration

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