

PATIENT INFORMATION
YUWIWEL® (YOU-vih-well)
(navepegritide)
For subcutaneous use only

What is YUWIWEL?

YUWIWEL is a prescription medicine used to increase linear growth in children 2 years of age and older with achondroplasia whose growth plates (epiphyses) are open.

Before you give YUWIWEL to your child, tell the healthcare provider about all of your child's medical conditions, including if your child:

- has kidney problems.
- is pregnant or plans to become pregnant. It is not known if YUWIWEL will harm the unborn baby.
- is breastfeeding or plans to breastfeed. It is not known if YUWIWEL passes into the breast milk. Talk to your child's healthcare provider about the best way to feed your child's baby, if your child receives YUWIWEL.

Tell the 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 YUWIWEL?

Read the detailed Instructions for Use that comes with your child's YUWIWEL for information on how to store, prepare, and give YUWIWEL, as well as how to throw away (dispose of) YUWIWEL the right way.

- Use YUWIWEL exactly as instructed by your child's healthcare provider.
- If YUWIWEL has been stored in the refrigerator, let the vial and Prefilled Diluent Syringe sit at room temperature for about 30 minutes before use.
- YUWIWEL is given as an injection under the skin (subcutaneous). YUWIWEL can be injected in either the stomach area (2 inches from the belly button) or thighs. If a caregiver gives the YUWIWEL injection, the buttocks or the back of the upper arms can be used as injection sites. Choose a different injection site each time. Avoid injecting where skin is red, swollen, or scarred.
- Your child's healthcare provider will show you how to prepare and inject YUWIWEL the right way before you use it for the first time at home.
- Inject YUWIWEL 1 time each week on the scheduled dosing day. You can choose any time during the day to give your child the injection.
- If your child misses a dose of YUWIWEL, give the missed dose as soon as possible but not more than 2 days after the missed dosing day. To avoid missed doses, YUWIWEL can be given up to 2 days before or 2 days after the scheduled dosing day. If more than 2 days have passed, your child should skip the missed dose, and the next dose should be given on the regularly scheduled dosing day. In both cases, your child can go back to the regular 1 time each week dosing schedule. At least 5 days must pass between doses.
- In case you are not sure when to inject YUWIWEL, call your child's healthcare provider or pharmacist. Do not give YUWIWEL more often than as directed by the healthcare provider.
- Your child's dose of YUWIWEL depends on body weight. The healthcare provider will tell you which strength of YUWIWEL to use and how much to give to your child.
- Your healthcare provider will monitor your child's growth and instruct you on when your child should stop using YUWIWEL if they determine that your child is no longer able to grow. Stop giving YUWIWEL to your child if instructed by your child's healthcare provider.

What are the possible side effects of YUWIWEL?

YUWIWEL may cause serious side effects, including:

- **risk of low blood pressure.** If your child experiences a decrease in blood pressure or symptoms of low blood pressure (dizziness, feeling tired, and/or nausea) while being treated with YUWIWEL, call your child's healthcare provider.

The most common side effects of YUWIWEL include:

Injection site reactions like redness, itching, skin discoloration, bleeding, swelling, bruising, pain and small fluid-filled blisters that form at the injection site.

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

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

How should I store YUWIWEL?

- Store YUWIWEL in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- Do not freeze YUWIWEL.
- YUWIWEL can also be stored at room temperature up to 86°F (30°C) for up to 6 months and can be returned to the refrigerator within the 6 months. Do not use YUWIWEL past the expiration date or 6 months after the date it was first removed from the refrigerator (whichever comes first).
- **After mixing**, YUWIWEL can be stored at room temperature up to 86°F (30°C) and must be used within 4 hours. Throw away unused medicine. Throw away medicine if not used within 4 hours after mixing.

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

General information about the safe and effective use of YUWIWEL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use YUWIWEL for a condition for which it was not prescribed. Do not give YUWIWEL to other people, even if they have the same symptoms that your child has. It may harm them. You can ask a pharmacist or healthcare provider for information about YUWIWEL that is written for health professionals.

What are the ingredients in YUWIWEL?

Active ingredients: navepegritide

Inactive ingredients: succinic acid, trehalose dihydrate, tromethamine and hydrochloric acid. The diluent contains Sterile Water for Injection, USP.

Manufactured for:
Ascendis Pharma Growth Disorders A/S
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DK-2900 Hellerup, Denmark

For more information, go to www.YUWIWEL.com, or call Ascendis Signature Access Program® (A-S-A-P) at 1-844-442-7236. Ascendis Pharma Endocrinology Inc., Princeton, New Jersey 08540, USA

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