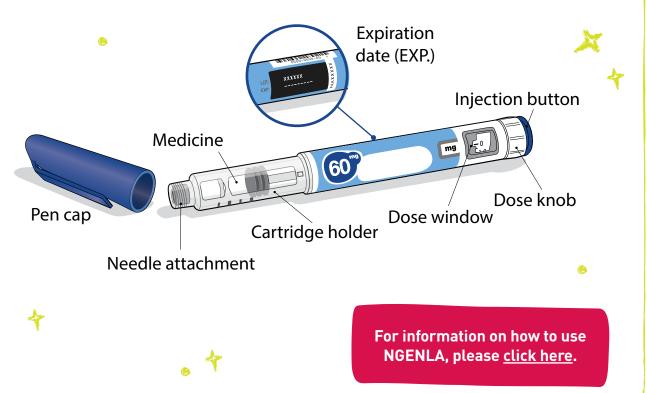
# TABLETOP GUIDE TO USING YOUR NGENLA PEN





Please read the **full NGENLA Instructions for Use** before you use your device. If you have any questions about your dose or treatment, or if there is anything you do not understand, please call your child's doctor or the Pfizer Bridge Program® at 1-800-645-1280.



# SUPPLIES YOU WILL NEED EACH TIME YOU INJECT NGENLA

#### Included in the carton:

• 1 NGENLA prefilled pen (either 24 mg or 60 mg, depending on your child's weight)

#### Not included in the carton:

- 1 new sterile needle for each injection
- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandage
- 1 FDA-cleared sharps disposal container for disposal of pen needles and pens

#### Tips:

- Do not shake your pen
- For a more comfortable injection, leave your pen at room temperature for up to 30 minutes
- Do not use your pen if:
  - It has been frozen or exposed to heat
  - It has been dropped
- It looks broken or damaged
- It has been more than 28 days after first use of pen

#### **INDICATION**

NGENLA is a prescription product for the treatment of growth failure in children 3 years of age and older who do not make enough growth hormone on their own. This condition is called growth hormone deficiency (GHD).

#### **SELECTED SAFETY INFORMATION**

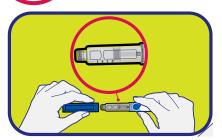
Growth hormone should not be used in children after the growth plates have closed.

Please see full Important Safety Information on last page and full Prescribing Information.



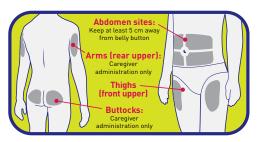
#### **ASSEMBLING YOUR NGENLA PEN**

**REMINDER:** Always <u>wash your hands</u> with soap and water and dry them well before handling your pen.



# **Get ready**

- Wash and dry your hands
- Use the pen straight from the refrigerator. For a more comfortable injection, leave it at room temperature for up to 30 minutes
- Check the expiration date on the pen label. Do not use if the expiration date has passed



# 2 Choose and clean your injection site

- Injection should be given in the abdomen, front of the upper thighs, buttocks, or rear of the upper arms
- If more than 1 injection is needed, each injection should be given in a different injection site
- Do not inject into bony areas; areas that are bruised, red, sore, or hard; or areas that have scars or skin conditions
- Clean the injection site with an alcohol swab and let dry
- Do not touch injection site after cleaning





# **3** Check medicine and prepare your injection

- Pull off the pen cap and set it aside for after the injection. Check the medicine's color. It should be clear to slightly light yellow and free of flakes or particles. Do not inject if medicine is cloudy, dark yellow, or has flakes or particles
- Take a new needle and pull off its protective paper. Attach a new needle for each injection
- Pull off the outer needle cover. Set it aside for later to help remove the needle
- Pull off the inner needle cap. Throw it away in a sharps container

# **IMPORTANT: Priming a new pen**

If you're using this pen for the first time, you'll need to prime it by following these instructions. (If you've used this pen before, skip to Step 4.) The purpose of priming is to remove air bubbles and make sure you get the correct dose.

### If you turn the dose knob too far, you can turn it back.

- Point the pen needle up and tap the holder to get rid of any air bubbles. Follow this step even if bubbles are not visible
- Holding the needle upward, press the injection button completely until you see "0" in the dose window. Once you see liquid at the needle tip, your pen is set up
- If liquid does not appear after repeating these steps 5 times, attach a new needle and try 1 more time. Do not use the pen if liquid still does not appear



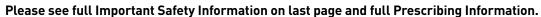
**To prime a 24 mg pen**, first turn the dose knob to **0.4**.



To prime a 60 mg pen, turn the dose knob to 1.0.

#### **SELECTED SAFETY INFORMATION**

Growth hormone should not be used in children with some types of eye problems caused by diabetes (diabetic retinopathy).





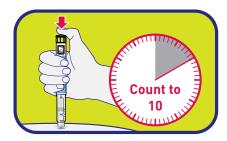


## **SETTING YOUR DOSE AND ADMINISTERING YOUR INJECTION**



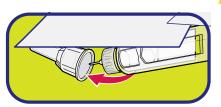
# Set your prescribed dose

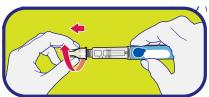
- Turn the knob to set your dose; dose knob turns 0.2 mg at a time for the NGENLA 24-mg pen and 0.5 mg at a time for the NGENLA 60-mg pen
- Check the dose window to make sure you have set the correct dose.
   Important: Do not press the injection button while setting your dose
- If your dose is more than 30 mg when using the NGENLA 60-mg pen, or more than 12 mg when using the NGENLA 24-mg pen, you will need more than 1 injection. Only split your dose if you have been trained or advised by your health care provider on how to do this. Use a new needle for each injection



## **5** Inject your dose

- Hold the pen so you can see the numbers in the dose window
- Insert the needle straight into the skin at a 90-degree angle
- Press the injection button until it can't go down any further and "0" is shown in the dose window. Continue to press the injection button while counting to 10. Counting to 10 will allow the full dose of medicine to be given
- After counting to 10, let go of the injection button and remove the pen from the injection site by pulling the needle straight out
- Be sure to rotate the injection site each week





# 6 Finish up

- Carefully place the outer needle cover back on the needle.

  Press on the outer needle cover until it is secure
- Unscrew the capped needle from the pen, and gently pull until the capped needle comes off
- Dispose of the capped needle in a sharps container. Do not reuse needles
- Replace the pen cap. If there is any medicine left, store it in the refrigerator between uses



#### **SELECTED SAFETY INFORMATION**

Growth hormone should not be used in children who have cancer or other tumors.

Growth hormone should not be used in children who are critically ill because of some types of heart or stomach surgery, trauma, or breathing (respiratory) problems.

Please see <u>full Important Safety Information</u> on last page and full Prescribing Information.



Not an actual patient.





# The Pfizer Bridge Program can support you in several ways:

- Device training (in-home or virtual) by an experienced nurse
- Assist with understanding the insurance process
- Arrange for the first NGENLA shipment from the pharmacy and address issues that may lead to pharmacy delays or treatment interruptions
- Provide eligible, commercially insured patients with financial assistance and savings

The program includes a Patient Care Consultant. They will work directly with your doctor, insurance, and pharmacy to help your child get started on NGENLA as soon as possible.

**Have questions?** Contact the Pfizer Bridge Program at **1-800-645-1280**.



#### **INDICATION**

NGENLA is a prescription product for the treatment of growth failure in children 3 years of age and older who do not make enough growth hormone on their own. This condition is called growth hormone deficiency (GHD).



#### **IMPORTANT SAFETY INFORMATION**

Growth hormone should not be used in children after the growth plates have closed.

Growth hormone should not be used in children with some types of eye problems caused by diabetes (diabetic retinopathy).

Growth hormone should not be used in children who have cancer or other tumors.

Growth hormone should not be used in children who are critically ill because of some types of heart or stomach surgery, trauma, or breathing (respiratory) problems.

Growth hormone should not be used in children with Prader-Willi syndrome who are very overweight or have breathing problems including sleep apnea.

NGENLA should not be used by children who have had an allergic reaction to somatrogon-ghla or any of the ingredients in NGENLA. Look for prompt medical attention in case of an allergic reaction.

Some children have developed diabetes mellitus while taking growth hormone. Dosages of diabetes medicines may need to be adjusted during treatment with NGENLA. Children should be watched carefully if NGENLA is given along with glucocorticoid therapy and/or other drugs that are processed by the body in the same way.

In childhood cancer survivors, treatment with growth hormone may raise the likelihood of a new tumor, particularly some benign (non-cancerous) brain tumors. This likelihood may be higher in children who were treated with radiation to the brain or head. Your child's health care provider will need to check your child for a return of cancer or a tumor.

Children treated with growth hormone have had increased pressure in the brain. If your child has headaches, eye problems, nausea (feeling like you are going to be sick), or vomiting, contact your child's health care provider.

NGENLA may decrease thyroid hormone levels. Decreased thyroid hormone levels may change how well NGENLA works. Your child's health care provider will do blood tests to check your child's hormone levels.

Children treated with growth hormone should be checked regularly for low serum cortisol levels and/or the need to increase the dose of the glucocorticoids they are taking.

In children experiencing fast growth, curvature of the spine may develop or worsen. This is also called scoliosis. Children with scoliosis should be checked regularly to make sure their scoliosis does not get worse during their growth hormone therapy.

Use a different area on the body for each injection. This can help to avoid skin problems such as lumpiness or soreness.

Growth hormone treatment may cause serious and constant stomach (abdominal) pain. This could be a sign of pancreatitis. Tell your child's health care provider if your child has any new stomach (abdominal) pain.

In studies of NGENLA in children with GHD, side effects included injection site reactions such as pain, swelling, rash, itching, or bleeding. Other side effects were the common cold, headache, fever (high temperature), low red blood cells (anemia), cough, vomiting, decreased thyroid hormone levels, stomach pain, rash, or throat pain.

A health care provider will help you with the first injection. He or she will also train you on how to inject NGENLA. Rx only

Please see full Prescribing Information.



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