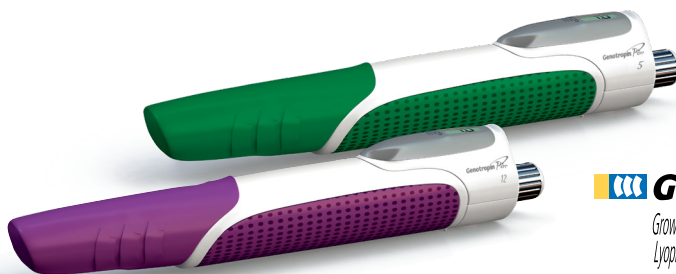


Instructions for using **GENOTROPIN Pen**[®]



Important Note: Please read the **full GENOTROPIN Pen Instructions for Use** before you use your device. **If there is anything you do not understand or cannot do, please call your health care provider or Pfizer Bridge Program[®] at 1-800-645-1280.**

If you have any questions about your dose or your treatment with GENOTROPIN, **please contact your health care provider.**

INDICATIONS

GENOTROPIN is a prescription product for the treatment of growth failure in children:

- Who do not make enough growth hormone on their own. This condition is called growth hormone deficiency (GHD)
- With a genetic condition called Prader-Willi syndrome (PWS). Growth hormone is not right for all children with PWS. Check with your doctor
- Who were born smaller than most other babies born after the same number of weeks of pregnancy. Some of these babies may not show catch-up growth by age 2 years. This condition is called small for gestational age (SGA)
- With a genetic condition called Turner syndrome (TS)
- With idiopathic short stature (ISS), which means that they are shorter than 98.8% of other children of the same age and sex; they are growing at a rate that is not likely to allow them to reach normal adult height and their growth plates have not closed. Other causes of short height should be ruled out. ISS has no known cause

GENOTROPIN is a prescription product for the replacement of growth hormone in adults with growth hormone deficiency (GHD) that started either in childhood or as an adult. Your doctor should do tests to be sure you have GHD, as appropriate.

SELECTED SAFETY INFORMATION

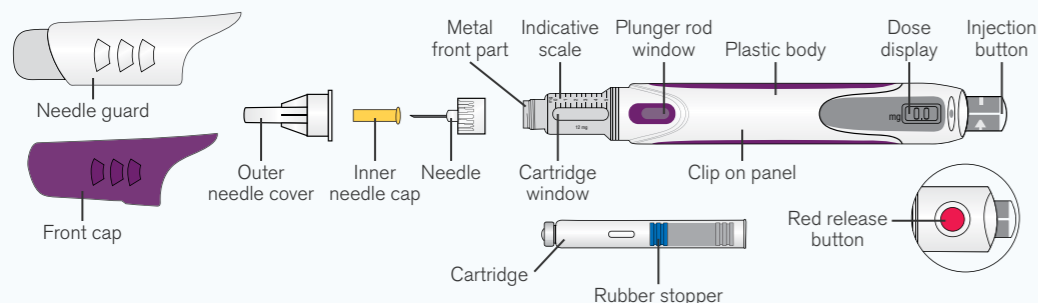
Growth hormone should not be used to increase height in children after the growth plates have closed.

Growth hormone should not be used in patients with diabetes who have certain types of diabetic retinopathy (eye problems).

Please see additional Selected Safety Information throughout and full Prescribing Information.

1 Getting Started

Parts of the GENOTROPIN Pen



A health care provider may help you with the first injection. He or she can also train you on how to inject GENOTROPIN.

GENOTROPIN cartridges contain m-Cresol and should not be used by patients allergic to it.

For each injection you will need:

- 1 GENOTROPIN PEN 5 or PEN 12 device
- 1 GENOTROPIN 5 mg or 12 mg 2-chamber cartridge
- 1 new 29 gauge (29 G), 30 gauge (30 G), or 31 gauge (31 G) Becton Dickinson pen needle
- Alcohol swab (not included)
- 1 sharps disposal container (not included)

SELECTED SAFETY INFORMATION (continued)

Growth hormone should not be used in patients who have been recently diagnosed with cancer, with cancer, or who are being treated for cancer. Growth hormone deficiency can be caused by brain tumors. So, the presence of these brain tumors should be ruled out before treatment is started. Growth hormone should not be used if it is shown that a previous brain tumor has come back or is getting larger.

Growth hormone should not be used in patients who are critically ill because of surgery, trauma, or respiratory failure.

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

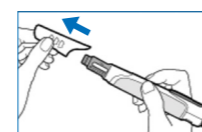
GENOTROPIN should not be used by patients who have had an allergy or bad reaction to somatropin or any of the other ingredients in GENOTROPIN. In the event of an allergic reaction, seek prompt medical attention.

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

2 Preparing Your GENOTROPIN Pen

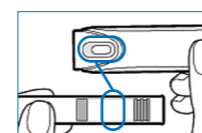
Wash your hands with soap and water, then follow the steps below.

Attach the Needle



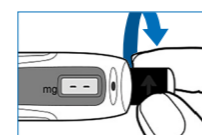
- Pull off front cap
- Turn the metal front part to the right to unscrew
- Peel foil off
- Hold the outer needle cover, and push and screw the needle onto the metal front part by turning it to the left. Do not remove the needle cover or cap

Insert Cartridge



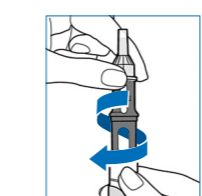
- Use only the 5 mg or 12 mg cartridge provided.
- Open the cartridge pack and take 1 cartridge out
- Make sure the color matches the color of the window on the plastic body
- Hold metal front part upright and insert the end of the cartridge with the metal cap. Push firmly into place

Prepare the Pen



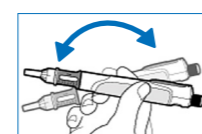
- Press red release button; the injection button will pop up
- Turn injection button to the left as far as it will go. This will draw back the plunger rod
- Make sure plunger rod is not visible through the plunger rod window. **Do not** continue if it is visible, as this means the medicine won't be properly mixed

Mix Your GENOTROPIN



- Hold pen upright and gently screw metal front part and plastic body together
- Make sure metal front part is firmly attached to plastic body as this mixes the liquid and powder

Examine the Solution



- Gently tip pen from side to side to dissolve powder
- **Do not shake** pen, as this might stop the medicine from working. Check that the solution is clear in the cartridge window
- If the solution is not clear, **do not inject**. Remove cartridge and use a new one

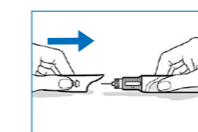
Release Trapped Air



- Remove and throw away outer needle cover and inner needle cap. **Do not touch** the exposed needle
- Remove any trapped air from the solution by doing the following:
 - a. Turn the injection button so the white mark lines up with the black mark on the plastic body
 - b. Hold pen with needle pointing up. Gently tap metal front part to move any air bubbles to the top
 - c. Push injection button all the way in. You will see a drop of liquid at the top of the needle
 - d. If you do not see any liquid, press the red release button. Then turn the injection button in the direction of the arrow until it clicks 1 time and the dose display shows "0.1" (Pen 5) or "0.2" (Pen 12). Repeat steps b. and c. if air remains trapped

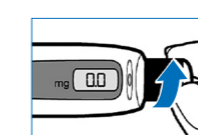
3 Injecting Your GENOTROPIN Pen

Attach Needle Guard (optional)



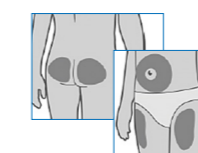
- The needle guard is intended to hide the needle before, during, and after injection and to reduce needle injury. You can choose to use the needle guard, if desired
- Grip the sides of the needle guard and push it over the needle until it snaps into place. **Do not** push the needle guard on the end

Dial Your Dose



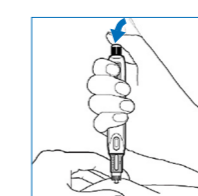
- Press the red release button; button will pop up and the dose display window will show "0.0"
- Turn injection button to the right until your prescribed dose is shown. If you turn too far, turn it back the other way until you get to your correct dose

Select Injection Site



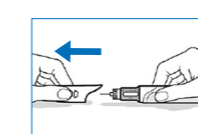
- Choose an injection site. The highlighted areas mark places where the injection can be given. Use a different site each time. Each new injection should be at least 1 inch from the site used before
- Avoid areas that are bony, bruised, red, sore, or hard. Also avoid areas that have scars or skin problems
- Clean the injection site with the alcohol swab and allow it to dry

Inject Your GENOTROPIN



- Firmly pinch a fold of skin at the injection area. Push the needle fully into the fold at a 90° angle
- Push the injection button until it clicks. Wait 5 seconds, and then remove the needle

Finish Up



- Pull off the needle guard, gripping the sides. Be careful not to push on the end
- Do not reuse the needle. Remove it and throw it away in an official sharps disposal container or a heavy-duty plastic container that is:
 - Closed with a puncture-resistant, tight-fitting lid that doesn't allow sharps to come out
 - Leak resistant, upright, and stable during use
 - Properly labeled to warn of hazardous waste inside the container
- **Do not** throw needles away in household trash
- Follow your community guidelines for disposing of your full sharps containers. For information about safe disposal in your state, go to the FDA's website at: www.fda.gov/safesharpsdisposal
- Push on the front cap and put pen back in its protective case
- Store pen (with cartridge) in the refrigerator between 36°F and 46°F (2°C-8°C) until your next injection
- **Important:** Always keep the sharps disposal container out of the reach of children

Please see Indications on front, additional Selected Safety Information throughout, and full Prescribing Information.

 **Genotropin**[®]
(somatropin) for injection

SELECTED SAFETY INFORMATION (continued)

In childhood cancer survivors, treatment with growth hormone may increase the risk of a new tumor, particularly certain benign brain tumors. This risk may be higher in patients who were treated with cranial radiation. Also, patients and their doctors should check regularly for skin changes.

A small number of patients treated with growth hormone have had increased pressure in the brain. This can cause headaches and problems with vision. Treatment should be stopped and reassessed in these patients. Patients with Turner syndrome and Prader-Willi syndrome may be at higher risk of developing increased pressure in the brain.

Thyroid function should be checked regularly during growth hormone therapy. Thyroid hormone replacement therapy should be started or adjusted if needed.

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

In children experiencing rapid growth, limping or hip or knee pain may occur. If a child getting growth hormone therapy starts to limp or gets hip or knee pain, the child's doctor should be notified and the child should be examined.

Growth hormone should only be used during pregnancy if clearly needed. It should be used with caution in nursing mothers because it is not known whether growth hormone is passed into human milk.

Use a different place on the body each day for growth hormone injections. This can help to prevent skin problems such as lumpiness or soreness.

Some cases of pancreatitis (inflamed pancreas) have been reported rarely in children and adults receiving growth hormone. There is some evidence that there is a greater risk of this in children than in adults. Literature suggests that girls who have Turner syndrome may have a greater risk of pancreatitis than other children taking growth hormone. In any child who develops lasting, severe abdominal pain, pancreatitis should be considered.

In studies of GENOTROPIN in children with GHD, side effects included injection site reactions, such as pain, redness/swelling, inflammation, bleeding, scarring, lumps, or rash. Other side effects were fat loss, headache, blood in the urine, low thyroid activity, and mildly increased blood sugar.

In studies of GENOTROPIN in children born SGA, side effects included temporarily elevated blood sugar, increased pressure in the brain, early puberty, abnormal jaw growth, injection site reactions, growth of moles, and worsening of scoliosis (curvature of the spine).

Deaths have been reported with the use of growth hormone in children with Prader-Willi syndrome. These children were extremely overweight, had breathing problems, and/or lung infection. All patients with Prader-Willi syndrome should be examined for these problems. They should also establish healthy weight control.

In studies of GENOTROPIN in children with PWS, side effects included fluid retention, aggressiveness, joint and muscle pain, hair loss, headache, and increased pressure in the brain.

Turner syndrome patients taking growth hormone therapy may be more likely to get ear infections. This is also called otitis media.

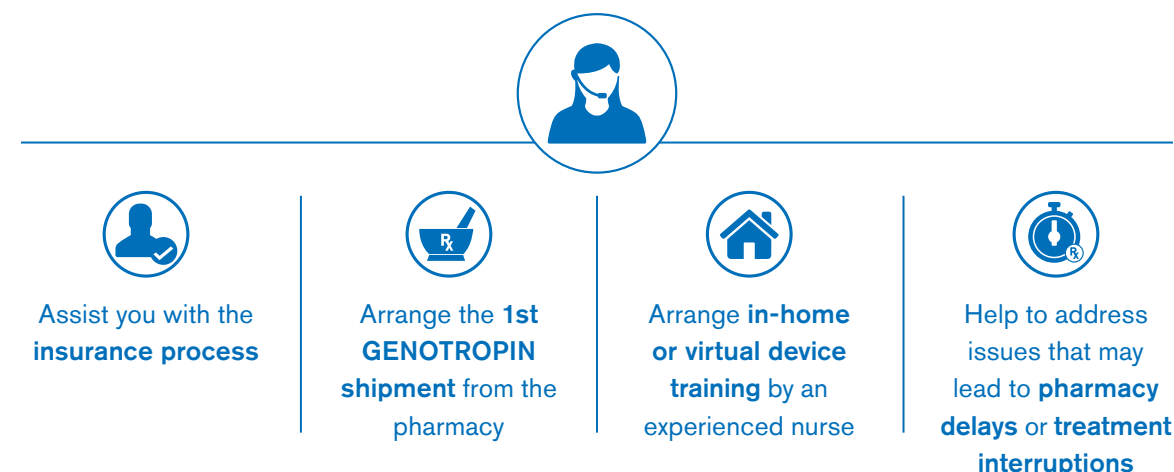
In studies of GENOTROPIN in children with Turner syndrome, side effects included flu, throat, ear, or sinus infection, runny nose, joint pain, and urinary tract infection.

In studies of GENOTROPIN in children with ISS, side effects included respiratory illnesses, flu, throat infection, inflammation of the nose and throat, stomach pain, headaches, increased appetite, fever, fracture, mood changes, and joint pain.

Women who are taking estrogen by mouth may take GENOTROPIN. They may need a larger dose of growth hormone.

THE PFIZER BRIDGE PROGRAM CAN SUPPORT YOU IN SEVERAL WAYS

The Pfizer Bridge Program can support you and your family through treatment. The support includes a dedicated Patient Care Consultant (PCC) who will work directly with your doctor, insurance, and pharmacy to help you get started on GENOTROPIN.



Contact the Pfizer Bridge Program at **1-800-645-1280**
PCCs are available 9 AM to 7 PM ET Monday-Friday

SELECTED SAFETY INFORMATION (continued)

GENOTROPIN may be taken by the elderly when appropriate. Elderly patients may be more likely to have side effects with growth hormone therapy.

In studies of GENOTROPIN in adults with GHD, side effects included fluid retention, joint or muscle pain, stiffness, and changes in sensation. Usually these side effects did not last long and depended on the dose of GENOTROPIN being taken.

GENOTROPIN cartridges contain m-Cresol and should not be used by patients allergic to it.

Use a different place on the body each day for growth hormone injections. This can help to prevent skin problems such as lumpiness or soreness.

A health care provider may help you with the first injection. He or she can also train you on how to inject GENOTROPIN.

Rx only

Please see Indications on front, additional Selected Safety Information throughout, and full Prescribing Information.