

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

**Genotropin Pen**[®]
Growth Hormone Delivery Device for Use With Genotropin[®]
Lyophilized Powder (somatropin) for injection

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 healthcare 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 healthcare provider.**

INDICATIONS

Genotropin (somatropin) is a prescription medicine that contains a form of human growth hormone and is used to treat:

- children who are not growing because of low or no growth hormone
- children who are not growing who have Prader-Willi syndrome (PWS)
- children who were born small for gestational age (SGA) and have not caught-up in growth by age 2
- children who are not growing and have Turner syndrome
- idiopathic short stature (ISS)
- adults who do not make enough growth hormone and have either adult onset or childhood onset growth hormone deficiency

IMPORTANT SAFETY INFORMATION

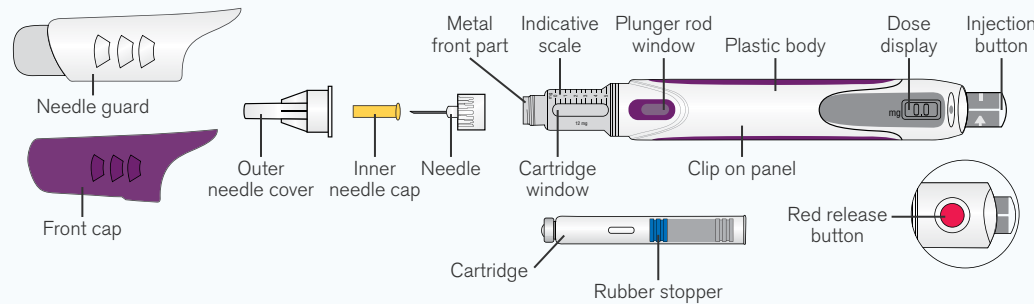
Do not use Genotropin if:

- you have a critical illness caused by certain types of heart or stomach surgery, trauma or breathing (respiratory) problems
- you are a child with Prader-Willi syndrome who is severely obese or has breathing problems including sleep apnea
- you have cancer or other tumors
- you are allergic to somatropin or any of the ingredients in Genotropin
- you have certain types of eye problems caused by diabetes (diabetic retinopathy)
- you are a child with closed bone growth plates (epiphyses)

Please see additional Important Safety Information on last page and full [Prescribing Information](#) at [genotropin.com](#)

1 Getting Started

Parts of the GENOTROPIN Pen



A healthcare 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.

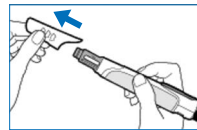
For each injection you will need:

- 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) pen needle (Becton Dickinson, Embecta, Terumo)
- Alcohol swab (not included)
- 1 sharps disposal container (not included)

2 Preparing Your GENOTROPIN Pen

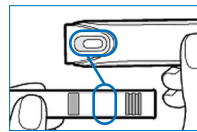
Wash your hands with soap and water, then follow the steps below.

2.1 Attach the Needle



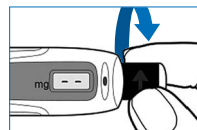
- Pull off front cap
- Turn the metal front part to the right to unscrew
- Peel foil off
- Hold the outer needle cover, and push and screw the needle onto the metal front part by turning it to the left. Do not remove the needle cover or cap until you are ready to inject

2.2 Insert Cartridge



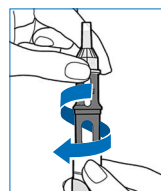
- Use only the 5 mg or 12 mg cartridge provided.
- Open the cartridge pack and take 1 cartridge out
 - Make sure the color matches the color of the window on the plastic body
 - Hold metal front part upright and insert the end of the cartridge with the metal cap. Push firmly into place

2.3 Prepare the Pen



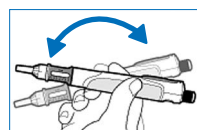
- Press red release button; the injection button will pop up
- Turn injection button to the left as far as it will go. This will draw back the plunger rod
- Make sure plunger rod is not visible through the plunger rod window. **Do not** continue if it is visible, as this means the medicine won't be properly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

2.4 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

2.5 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

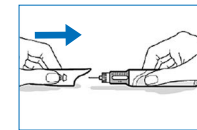
2.6 Release Trapped Air



- 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

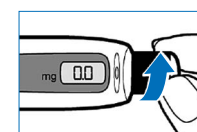
3 Injecting Your GENOTROPIN Pen

3.1 Attach Needle Guard (optional)



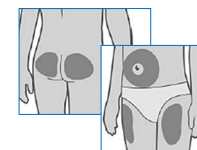
- The needle guard is intended to hide the needle before, during, and after injection and to reduce needle injury. You can choose to use the needle guard, if desired
- Grip the sides of the needle guard and push it over the needle until it snaps into place. **Do not** push the needle guard on the end

3.2 Dial Your Dose



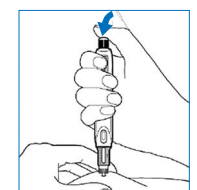
- Press the red release button; button will pop up and the dose display window will show "0.0"
- Turn injection button to the right until your prescribed dose is shown. If you turn too far, turn it back the other way until you get to your correct dose

3.3 Select Injection Site



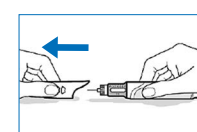
- Choose an injection site. The highlighted areas mark places where the injection can be given. Use a different site each time. Each new injection should be at least 1 inch from the site used before
- Avoid areas that are bony, bruised, red, sore, or hard. Also avoid areas that have scars or skin problems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

3.4 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

3.5 Finish Up



- Pull off the needle guard, gripping the sides. Be careful not to push on the end
- Do not reuse the needle
- 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

3.6 Disposal of Used Needle

- Throw the needle 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
- **Important:** Always keep the sharps disposal container out of the reach of children
- **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

Please see additional Important Safety Information on last page and full [Prescribing Information](http://www.genotropin.com) at [genotropin.com](http://www.genotropin.com)

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

THE PFIZER BRIDGE PROGRAM[®] CAN SUPPORT YOU IN SEVERAL WAYS

If your doctor has prescribed GENOTROPIN, 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 as soon as possible.

Contact the Pfizer Bridge Program at **1-800-645-1280**



Assist you with the
insurance process



Arrange the **1st
GENOTROPIN
shipment** from the
pharmacy



Arrange for
**device training
education** with an
experienced nurse



Address issues
that may lead to
**pharmacy delays
or treatment
interruptions**

Click here to enroll in the **GENOTROPIN** Copay Program

IMPORTANT SAFETY INFORMATION (continued)

Do not use Genotropin if:

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- you are a child with Prader-Willi syndrome who is severely obese or has breathing problems including sleep apnea
- you have cancer or other tumors
- you are allergic to somatropin or any of the ingredients in Genotropin
- you have certain types of eye problems caused by diabetes (diabetic retinopathy)
- you are a child with closed bone growth plates (epiphyses)

Before using Genotropin, tell your healthcare provider about all of your medical conditions, including if you:

- have had heart or stomach surgery, trauma or serious breathing (respiratory) problems
- have had a history of problems breathing while you sleep (sleep apnea)
- have or have had cancer or any tumor
- have diabetes
- have ear problems
- are pregnant or breastfeeding, or plan to become pregnant or breastfeed

Tell your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements. Genotropin may affect how other medicines work, and other medicines may affect how Genotropin works.

Genotropin may cause serious side effects, including:

- higher risk of death in people who have critical illnesses because of heart or stomach surgery, trauma or serious breathing (respiratory) problems
- risk of sudden death in children with Prader-Willi syndrome who are severely obese or have breathing problems including sleep apnea
- increased risk of the return of cancer or a tumor in people who were treated with radiation to the brain or head as children and who developed low growth hormone problems. Your healthcare provider will need to monitor you for a return of cancer or a tumor

- new or worsening high blood sugar (hyperglycemia) or diabetes. Your blood sugar may need to be monitored during treatment
- increase in pressure in the skull. If you have headaches, eye problems, nausea or vomiting, contact your healthcare provider
- serious allergic reactions. Get medical help right away if you have the following symptoms: swelling of your face, lips, mouth or tongue, trouble breathing, wheezing, severe itching, skin rashes, redness or swelling, dizziness or fainting, fast heartbeat or pounding in your chest, or sweating
- your body holding too much fluid (fluid retention) such as swelling in the hands and feet, pain in your joints or muscles or nerve problems that cause pain, burning, or tingling in the hands, arms, legs and feet. Tell your healthcare provider if you have any of these signs or symptoms of fluid retention
- decrease in a hormone called cortisol. Tell your healthcare provider if you have darkening of the skin, severe fatigue, dizziness, weakness or weight loss
- decrease in thyroid hormone levels. Decreased thyroid hormone levels may affect how well Genotropin works. Your healthcare provider will do blood tests to check your hormone levels
- hip and knee pain or a limp in children (slipped capital femoral epiphysis). This may lead to a serious condition where bone tissue dies due to a lack of blood supply (osteonecrosis). Get medical help right away if you develop a limp or has hip or knee pain
- worsening of pre-existing curvature of the spine (scoliosis). If you have scoliosis, you will need to be checked often for an increase in the curve of the spine
- increased risk of ear and hearing problems and heart problems if you have Turner syndrome
- loss of fat and tissue weakness in the area of skin you inject
- increase in phosphorus, alkaline phosphatase, and parathyroid hormone levels in your blood
- severe and constant abdominal pain. This could be a sign of pancreatitis. Tell your healthcare provider if you have any new abdominal pain

Other common side effects of Genotropin include:

- injection site reactions and rashes, loss of fat and tissue weakness, and headaches

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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