

Genotropin Pen® 12

Growth Hormone Delivery Device for use with Genotropin®
Lyophilized Powder (somatropin for injection)

Instructions for Use

GENOTROPIN 12 (JEEN-o-tro-pin 12)

GENOTROPIN PEN 12 is a medical device used to mix and inject doses of reconstituted GENOTROPIN Lyophilized Powder (somatropin) for injection. Use this device only for administration of GENOTROPIN.

Important Note

Please read these instructions completely before using the GENOTROPIN PEN 12. Please do not use the GENOTROPIN PEN 12 unless your Healthcare provider has trained you.

If there is anything you do not understand or cannot do, call the Pfizer Bridge Programs toll-free number at 1-800-645-1280.

If you have any questions about your dose or your treatment with GENOTROPIN, call your Healthcare provider.

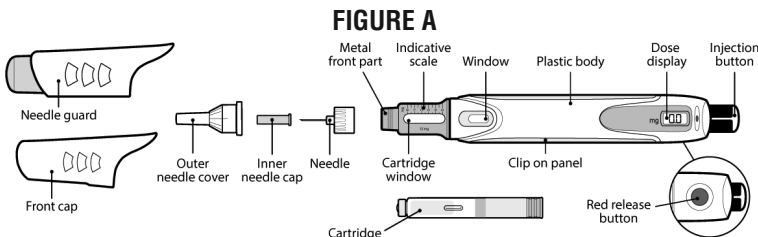
Your pen should not be used near electrical or electronic equipment, including mobile phones. If your pen has been damaged, it should not be used and should be disposed of as instructed by your Healthcare provider.

GENOTROPIN PEN 12 is a reusable multi-dose device holding a 2-chamber cartridge of GENOTROPIN, used to mix and inject GENOTROPIN during a 2 year use period.

For your injection you will need:

- GENOTROPIN PEN 12 (pen)
- 12 mg two-chamber cartridge of GENOTROPIN
- 29 gauge (29 G), 30 gauge (30 G), or 31 gauge (31 G) Becton Dickinson pen needle
- Proper disposal container for used needles

The diagram below identifies the different components of the GENOTROPIN PEN 12 (See Figure A).



Storage instructions for your GENOTROPIN PEN 12

- Between uses, store your pen (with cartridge) in the refrigerator [36°F to 46°F (2°C to 8°C)] in its protective case. Always remove the needle before storing.
- Do not freeze. Protect from light. Throw away the cartridge within 28 days after reconstitution – even if the cartridge is not empty.
- When travelling, keep your pen in its protective case and carry it in an insulated bag to protect it from heat or freezing. Put it back in the refrigerator as soon as possible.

Using your GENOTROPIN PEN 12

Step 1.

Wash your hands well with soap and water before using the GENOTROPIN PEN 12.

Step 2. Attach the Needle

- Pull off the front cap (See Figure B).

FIGURE B

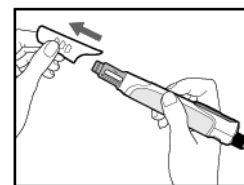
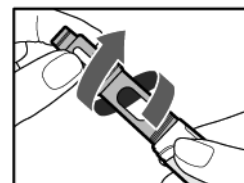
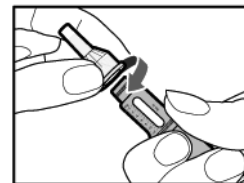


FIGURE C



- Unscrew the metal front part from the plastic body (See Figure C).

FIGURE D



- Peel off the foil from the needle.
- Push and screw the needle onto the metal front part (See Figure D).

Step 3. Insert the Two-Chamber Cartridge of GENOTROPIN

Use only the 12 mg cartridge.

- Open the cartridge pack and take out a cartridge.
- Check that the colour on the cartridge matches the colour around the plastic body window (See Figure E).
- Hold the metal front part upright, and insert the cartridge—metal cap first—as shown (See Figure F).
- Push the cartridge firmly into place.

FIGURE E

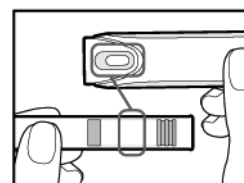


FIGURE F

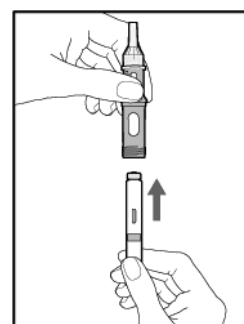
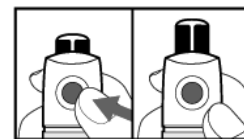


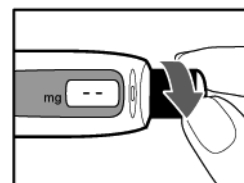
FIGURE G



Step 4. Prepare the Pen

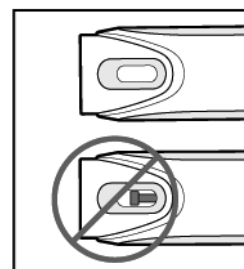
- Press the red release button; the injection button will pop-up (See Figure G).

FIGURE H



- Turn the injection button as far as it will go in the opposite way to the arrows on the injection button. This will draw back the plunger rod (See Figure H).

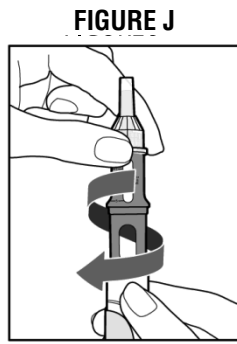
FIGURE I



- **Check that the plunger rod is not visible through the window. Do not proceed if the plunger rod is visible, as the medication will not be properly mixed (See Figure I).**

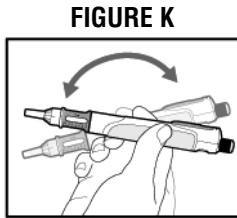
Step 5. Mix your GENOTROPIN

- Make sure that a needle is attached to the metal front part.
- While holding your pen **upright**, gently screw the metal front part and the plastic body back together. This mixes the liquid and the powder (See Figure J).

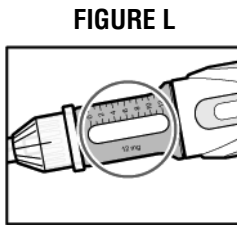


Step 6. Examine the Solution

- Gently tip the pen from side to side to help dissolve the powder completely (See Figure K).



- **Do not shake** your pen, as this might stop the growth hormone working. Check that the solution is clear in the cartridge window (See Figure L).

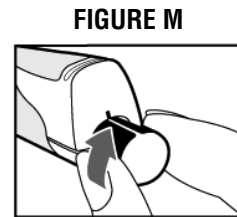


If you see particles, or if the solution is not clear, **do not inject it**. Instead, remove the cartridge and use a new one.

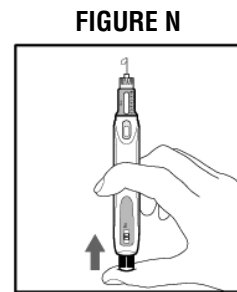
Step 7. Release Trapped Air

- Remove both the outer needle cover and inner needle cap. Dispose of the inner needle cap. Be careful **not to touch** the exposed needle.
- Remove any trapped air from the solution as follows:

a) Turn the injection button so that the white mark on the injection button lines up with the black mark on the plastic body (See Figure M).



b) Hold your pen with the needle pointing **upwards**. Gently tap the metal front part with your finger to move any air bubbles to the top.



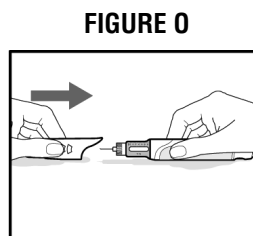
c) Push the injection button all the way in. You will see a drop of liquid appear at the needle tip. Any trapped air has now been released (See Figure N).

d) If no liquid appears, press the red release button. Then turn the injection button in the direction of the arrow until it clicks once and the display shows '0.2'. Repeat steps b) and c).

Step 8. Fit the 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. Push it over the needle until it snaps in place (See Figure O). Never push the needle guard on the end.

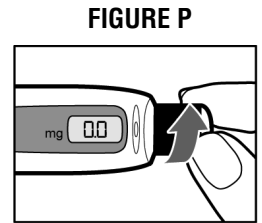


Be careful not to touch the exposed needle.

My daily dose is mg (write in your daily dose)

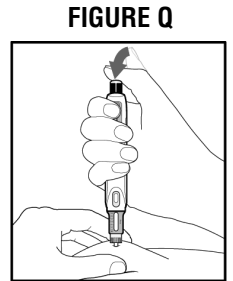
Step 9. Dial Your Prescribed Dose

- Press the red release button to reset your pen.
- The button will pop-up and the dose display window will read '0.0'.
- Turn the injection button (in the direction of the arrow) until your prescribed dose is displayed (See Figure P).
- If you turn the button too far, turn it back the other way until your correct dose is displayed.



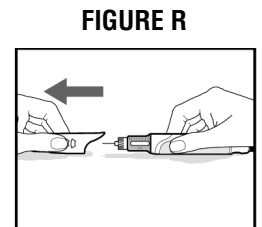
Step 10. Inject your GENOTROPIN

- Choose and prepare an appropriate injection area, as directed by your Healthcare provider.
- Firmly pinch a fold of skin at the injection area. Push needle fully into the skin fold at a 90° angle.
- Push the injection button until it clicks. Wait at least 5 seconds, and then withdraw the needle from the skin. This makes sure the entire dose has been injected (See Figure Q).



Step 11. Discard the Needle and Store the GENOTROPIN PEN 12

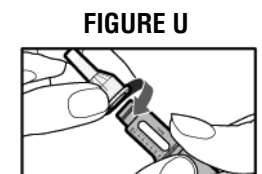
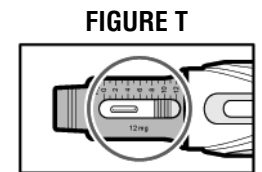
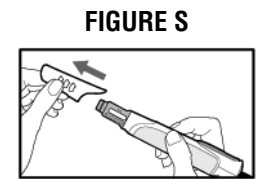
- Pull off the needle guard, gripping the sides. Be careful not to push on the end (See Figure R).
- Remove the needle as instructed by your Healthcare provider, and discard it in a proper disposal container. **Never reuse a needle.**
- Push on the front cap, and put your pen back in its protective case.
- Store your pen (with cartridge) in the **refrigerator** [36°F to 46°F (2°C to 8°C)] until your next injection.



Step 12. Your Next Injection

If you already have a cartridge in your pen, prepare the pen and give the injection as follows:

- Remove the front cap (See Figure S).
- Make sure there is enough growth hormone in the cartridge for your dose. Check the position of the plunger against the indicative scale in the cartridge window (See Figure T).
- Peel off the foil from a needle.
- Push and screw the needle onto the metal front part of your pen. Remove the outer needle cover and inner needle cap (See Figure U).
- Follow the instructions above, starting with Step 8: Fit the needle guard.



Step 13. To Replace the Cartridge

- Press the red release button to reset your pen (See Figure V).
- Turn the injection button (in the opposite direction to the arrow on the injection button) as far as it will go (See Figure W). This will draw back the plunger rod.
- Unscrew the metal front part and remove the empty cartridge (See Figure X).
- Discard the empty cartridge as instructed by your Healthcare provider.
- To insert a new cartridge and prepare your pen for reuse, follow the instructions starting with Step 1.

FIGURE V

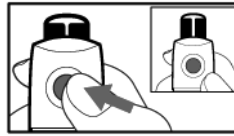


FIGURE W

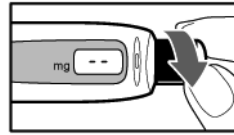


FIGURE X



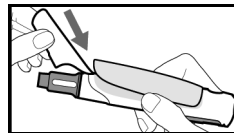
Step 14. Disposing of used Needles, cartridges and your GENOTROPIN PEN 12

- Your Healthcare provider will instruct you on how to discard your used needles and other medical waste in an appropriate puncture resistant disposal container such as sharps (medical waste) container. You may also contact your local health department for more information. There may be special state or local laws for properly disposing of used needles, other medical waste and sharps containers.
- **Do not** throw needles or sharps containers in the household trash without first checking your state and local laws.
- **Do not** recycle the sharps container.
- Always keep your sharps container in a safe place and out of reach of children.

Customizing your Pen

Your pen is supplied with two colored clip-on panels, enabling you to customize the look of your pen. To remove the clip-on panel from your pen, insert the lip of the front cap into the groove under the front end of the panel, and pry the panel off. The new panel simply clicks into place. A small hole near the dose display enables you to attach decorations or charms.

FIGURE Y



Caring for your Pen

No special maintenance is required. To clean your pen, wipe the outside surface with a damp cloth. Do not immerse. Do not use alcohol or any other cleaning agents, as they may damage the plastic body. To clean the needle guard, wipe it with a damp cloth or alcohol swab.

Questions and Answers	
Question	Answer
How long is the use period of my pen?	The pen has a use period of 2 year starting from the first use by the patient.
How can I tell how much GENOTROPIN is left in my pen?	The indicative scale along the side of the cartridge window is a guide. The number that aligns with the front edge of the rubber stopper shows you how many milligrams are left in the cartridge. If your cartridge is nearly empty you can also dial the injection button until it can't go any further; the dose display will then show the maximum dose that can be delivered. When the cartridge is empty, the injection button will not turn any further.
If the display doesn't work, can my pen still be used?	Yes, but it is not recommended. When the display or the battery doesn't function any more, it is still possible to set the dose of your pen by counting the clicks (one click = '0.2' mg). Your pen can still be used while waiting for a new one. Contact your Healthcare provider.

Questions and Answers (continued)	
Question	Answer
What happens if I dial the injection button beyond the maximum dose ('4.0' mg)?	Some liquid may appear from the needle tip, and the numbers may disappear from the dose display. This is normal and will not affect your injection. To correct this, turn the injection button in the direction of the arrow until numbers reappear on the dose display. Then dial back to your correct dose.

Display Information

Steady		The selected dose size. The number indicates the dose size (in mg) that your pen will deliver if the injection button is fully pressed in.
Steady		A dose is not set. The injection button has been turned too far in the opposite direction to the arrow on the injection button while setting the dose.
Flashing		The injection button is rotated too fast or too slow. Point the pen away from your face, press the injection button, press the red release button and continue preparing your dose.
Flashing		The injection button is rotated too fast or too slow. Point the pen away from your face, press the injection button, press the red release button and continue preparing your dose.
Flashing (5 seconds)		1 month before the 2nd year use elapse. This is normal. The dose can be set and read from the display. Contact your Healthcare provider.
Steady		Pen has reached the end of its use period of 2 years. The display will continue to show until the battery is completely empty. This does not indicate a defect of your pen. Your pen can still be used correctly, but the dose size will not be displayed. Contact your Healthcare provider.
Flashing (5 seconds)		Battery charge is low and will be empty in one month's time. Afterwards the dose can be set and your pen can be used correctly. Contact your Healthcare provider.
Steady		Battery power low. The dose cannot be displayed. Contact your Healthcare provider.
Steady		Blank screen To save the battery's energy, the dose display is activated for two minutes and then automatically disappears. Although the display is no longer visible, the dose remains available for delivery.

If you have any questions about your dose or your treatment with GENOTROPIN, call your Healthcare provider right away.

Use this device only for the person for whom it was prescribed.

These Instructions for use have been approved by the U.S. Food and Drug Administration.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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