Instructions for Use GENOTROPIN MINIQUICK (JEEN-o-tro-pin MIN-ee-kwik) Growth Hormone Delivery Device containing Genotropin® Lyophilized powder (somatropin [rDNA] for injection)

Important Note

Please read these instructions completely before using GENOTROPIN MINIQUICK. If there is anything you do not understand or cannot do, call the Pfizer Bridge Program's toll-free number at 1-800-645-1280.

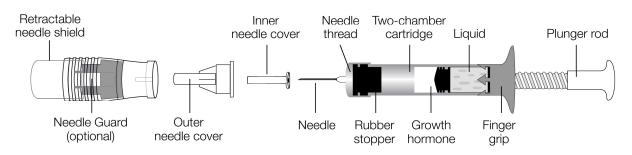
GENOTROPIN MINIQUICK is available in 10 dose strengths. Check your GENOTROPIN MINIQUICK to be sure you have the dose your doctor prescribed.

GENOTROPIN MINIQUICK is a device holding a 2-chamber cartridge of GENOTROPIN, used to mix and inject a single dose of GENOTROPIN.

For each injection you will need:

- 2 alcohol pads (not included)
- the GENOTROPIN MINIQUICK device with the 2-chamber cartridge of GENOTROPIN inside it. The 2-chamber cartridge of GENOTROPIN contains the growth hormone powder in one chamber and the liquid in the other.
- an injection needle. A needle for injection is provided with each device. If you need additional needles, ask for Becton Dickinson Ultra-Fine pen needles, either 29 gauge, 30 gauge or 31 gauge.
- the reusable Needle Guard (optional, not included)
- a proper disposal container (not included)

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



Storage instructions for your GENOTROPIN MINIQUICK

- Keep your GENOTROPIN MINIQUICK in the original carton to protect it from light.
- Before you mix the growth hormone powder with the liquid in the syringe, you can store the GENOTROPIN MINIQUICK in the refrigerator [36°F to 46°F (2°C to 8°C)]. However, you can also store the GENOTROPIN MINIQUICK at room temperature [68°F to 77°F (20°C to 25°C)] for up to three months. Do not freeze.
- Inject the GENOTROPIN right after you mix it. If that is not possible, you can keep the GENOTROPIN MINIQUICK in the refrigerator at 36°F to 46°F (2°C to 8°C) for up to 24 hours after mixing it. Do not freeze.

FIGURE A

Using your GENOTROPIN MINIQUICK

Step 1.

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

Step 2.

Open the plastic bag that contains your GENOTROPIN MINIQUICK, by tearing the bag along the perforated line on the plastic.

Step 3.

Wipe the rubber stopper on the GENOTROPIN MINIQUICK with a pad or swab moistened with rubbing alcohol. (See Figure B)

Peel the seal from the back of the injection needle. Leave both needle covers (inner and outer) on the needle. (See

FIGURE B

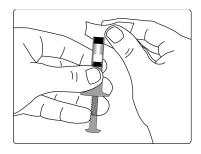


FIGURE C

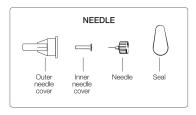


FIGURE D



Step 4.

Figure C)

- Attach the needle onto the GENOTROPIN MINIQUICK by pushing it down and turning it clockwise (to the right) until it will no longer turn.
- Make sure the needle is positioned squarely, not at an angle, onto the end of the rubber stopper before screwing it onto the GENOTROPIN MINIQUICK. (See Figure D)

Step 6.

- Hold the GENOTROPIN MINIQUICK with the needle pointing up. To mix the growth hormone powder with the liquid, turn the plunger rod clockwise (to the right) until it will not go any further. (See Figure E)
- When you turn the plunger rod clockwise (to the right), the GENOTROPIN MINIQUICK automatically mixes the growth hormone powder and the liquid.
- **Do not shake** the GENOTROPIN MINIQUICK. Shaking may cause the growth hormone to not work as well.
- Make sure the solution is clear, and that the growth hormone powder is completely dissolved. If you see particles in the solution, or if the solution is discolored, do not inject it. Call the toll-free number listed at the beginning of this leaflet.

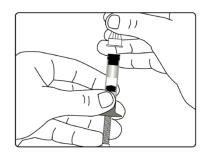
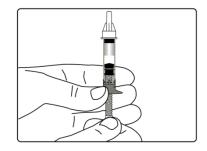


FIGURE E



Step 7.

- Select your injection site and wipe that area of your skin with an alcohol pad, as instructed by your healthcare provider.
- If you are using the reusable Needle Guard to hide the needle, go to Step 8.
- If you are not using the reusable Needle Guard, go to Step 9.

Step 8. – With Needle Guard

- Remove the outer needle cover from the needle, place the Needle Guard onto the GENOTROPIN MINIQUICK, and press gently until the Needle Guard snaps into place. Save the outer needle cover. (See Figure F)
- Remove the inner needle cover from the needle.
- Go to Step 10.

Step 9. - Without Needle Guard

- Remove the outer and inner needle covers from the needle. Save the outer needle cover. (See Figure G)
- Go to Step 10.

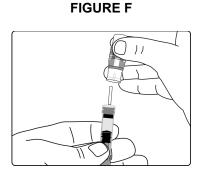


FIGURE G

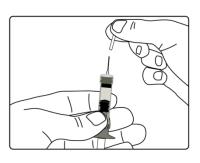
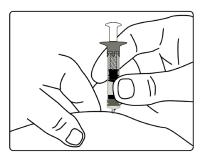


FIGURE H



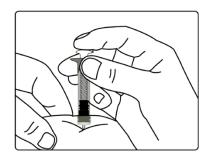
Step 10.

- Pinch a fold of skin at the injection site firmly, and push the needle straight into the skin at a 90-degree angle. (See Figure H)
- If you are using the optional Needle Guard, the retractable plastic needle shield will push in as the GENOTROPIN MINIQUICK is pushed against your skin.

Step 11

- Push the plunger rod in as far as it will go, to inject all the medicine in the GENOTROPIN MINIQUICK. (See Figure I)
- Wait a few seconds to be sure that all the growth hormone has been injected. Pull out the needle.

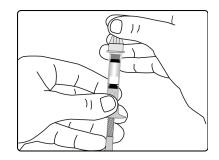
FIGURE I



Step 12.

- If you are using the Needle Guard, remove the Needle Guard and then carefully replace the outer needle cover on the needle. Save the Needle Guard for future use. (See Figure J)
- If you are not using the Needle Guard, carefully replace the outer needle cover on the needle.

FIGURE J



Step 13. Disposing of your GENOTROPIN MINIQUICK

- Your doctor or healthcare provider will instruct you on how to discard your used syringes and needles and other medical waste in an appropriate puncture resistant disposal container such as a 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, syringes, other medical waste, and sharps containers.
- **Do not** throw needles, syringes, 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 the reach of children.

Questions and Answers	
Question	Answer
Is it a problem if I see air bubbles in the syringe?	No. There is no need to remove the air from the GENOTROPIN MINIQUICK. The small amount of air in the syringe does not affect your injection.
What should I do if I have problems turning the plunger rod (Step 6)?	The problem could be because the needle has been inserted at an angle onto the rubber stopper.
	Carefully replace the outer needle cover on the needle and unscrew counterclockwise to remove the needle. Hold the GENOTROPIN MINIQUICK with the needle-end pointing up, and re-attach and screw the needle squarely on top of the device.
What should I do if I have problems pushing the	The problem could be because the needle has

plunger when making the injection (Step 11)?	been inserted at an angle onto the rubber stopper.
	Carefully replace the outer needle cover on the needle and unscrew counterclockwise to remove the needle. Hold the GENOTROPIN MINIQUICK with the needle-end pointing up, and re-attach and screw the needle squarely on top of the device.
What should I do if the needle is damaged or bent?	Throw away the needle and use a new needle with the GENOTROPIN MINIQUICK.
How do I care for my Needle Guard?	Clean the Needle Guard by wiping with a damp cloth or alcohol swab. If your Needle Guard does not function properly, call the Pfizer Bridge Program at 1-800-645-1280.

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.

Manufactured by: Vetter Pharma-Fertigung GmbH & Co. KG Ravensburg, Germany

Distributed by



Pharmacia & Upjohn Co Division of Pfizer Inc, NY, NY 10017

LAB-0227-5.0 Revised February 2012



Growth Hormone Delivery Device containing Genotropin® Lyophilized Powder (somatropin IrDNA origin) for injection)

PHARMACIA

Genotropin Pen® 12

Growth Hormone Delivery Device for use with Genotropin® Lyophilized Powder (somatropin [rDNA origin] for injection)

Instructions for Use

Important Note

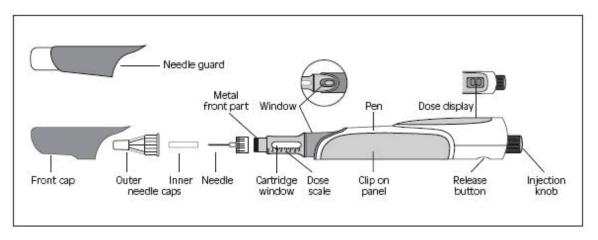
Please read these instructions completely before using the GENOTROPIN PEN 12. If there is anything you do not understand or cannot do, call the toll-free number listed at the end of these instructions. If you have any questions about your dose or your treatment with GENOTROPIN, call your healthcare provider.

GENOTROPIN PEN 12 is a device used to mix and inject doses of GENOTROPIN Lyophilized Powder (somatropin [rDNA origin] for injection). Use this device **only** for administration of GENOTROPIN.

What You Will Need

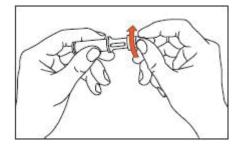
- GENOTROPIN PEN 12
- 12 mg two-chamber cartridge of GENOTROPIN
- Alcohol swab
- 29-gauge, 30-gauge, or 31-gauge Becton Dickinson pen needle
- Proper disposal container for used needles

Components of the GENOTROPIN PEN 12



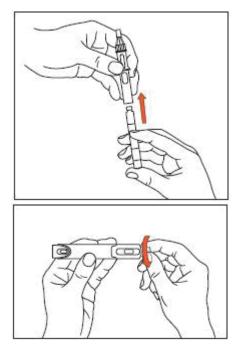
Before You Begin

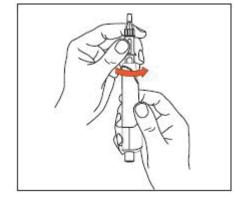
To help prevent infection, **always** wash your hands with soap and water before preparing or using the GENOTROPIN PEN 12.

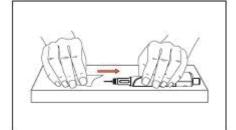


1. Attach the Needle

- Remove the front cap from the GENOTROPIN PEN 12.
- Unscrew the metal front part and detach it from the plastic body of the pen.
- Remove the paper covering from the back of a new needle.
- Screw the needle onto the metal front part by gently turning it clockwise (to the right).







2. <u>Insert the Two-Chamber Cartridge of</u> <u>GENOTROPIN</u>

- Use only the 12mg cartridge.
- Wipe the metal/rubber tip of the cartridge with an alcohol swab.
- Insert the cartridge into the metal front part of the pen, with the metal/rubber tip towards the needle end. Push the cartridge firmly into place.

3. <u>Prepare the Body of the Pen</u>

- Press the red release button to release the black/white injection knob.
- Turn the black/white injection knob counterclockwise (to the left) <u>as far as it will</u> <u>go.</u>
- Check that the plunger rod is not visible through the window at the top of the plastic body of the pen. Do NOT proceed if the plunger rod is visible, as the medication will not be properly mixed. Instead, press the red release button again to draw back the plunger rod. After the rod is no longer visible through the window, proceed to the next step.

4. Screw the GENOTROPIN PEN 12 Together

- Hold the metal front part upright.
- While holding upright, gently screw the metal front part and the plastic body back together. This mixes the diluent in the rear chamber of the cartridge with the growth hormone powder in the front chamber.
- Gently tip the assembled GENOTROPIN PEN 12 from side to side to help dissolve the powder completely. **DO NOT SHAKE** as that might inactivate the growth hormone.

5. Examine Solution and Release Trapped Air

- Look through the cartridge windows in the metal front part of the pen and make sure the drug solution is clear. If you see particles or if the solution is discolored, **DO NOT INJECT IT**. Instead, call the toll-free number listed at the end of these instructions.
- Remove the outer needle cap and save it for later.
- Remove and discard the inner needle cap. Be careful not to touch the exposed needle.
- Remove any trapped air from the solution as follows:
 - a) Turn the black/white injection knob clockwise (to the right) one click. This will line up the white mark on the injection knob and the black mark on the body of the pen.
 - b) Hold the GENOTROPIN PEN 12 upright and gently tap the metal front part with your finger to move any air bubbles to the top.

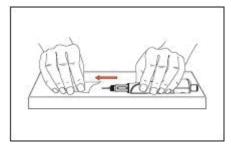
- c) Push the black/white injection knob all the way in. You will see a drop of liquid appear at the needle point. Any trapped air has now been released.
- d) If no liquid squirts out, press the red release button and turn the black/white injection knob clockwise (to the right) until it clicks once. Repeat steps b) and c).
- If desired, attach the reusable needle guard over the needle—push until it snaps in place. Again, be careful not to touch the exposed needle. To avoid an accidental needle stick, grip the sides of the needle guard; never push on the end.

6. <u>Dial Your Prescribed Dose</u>

- Press the red release button to reset the device.
- The black/white injection knob will pop out and the dose display window will read **0.0**.
- With the dose display activated, turn the black/white injection knob clockwise (to the right) until your prescribed dose is displayed.
- If you go too far, just turn the knob back the other way until the correct dose is displayed. NOTE: If you turn the black/white injection knob backwards beyond zero after a cartridge has been inserted, the pen display will show (--). Just turn the injection knob forward (clockwise) until numbers reappear on the dose display.
 - The GENOTROPIN PEN 12 contains a battery for the dose display. 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. NOTE: Each click of the black/white injection knob equals a two-tenth-of-a milligram dose (or 0.2 mg). One click-or 0.2 mg—is the minimum possible dose per injection; 20 clicks-or 4.0 mg-is the maximum possible dose per injection. If you accidentally dial more than the maximum 4.0 mg dose, some liquid may emerge from the tip. This is normal and will not affect your injection—simply dial back to the correct dose.

7. Inject your GENOTROPIN

- Select and prepare an appropriate injection site, as directed by your healthcare provider.
- Pinch a fold of skin at the injection site firmly, and push the GENOTROPIN PEN 12 into the skinfold at a 90° angle. Push the pen down as far as possible.
- Push the black/white injection knob until it clicks. Wait at least 5 seconds and then withdraw the GENOTROPIN PEN 12.



8. <u>Discard the Needle and Store the</u> <u>GENOTROPIN PEN 12</u>

- Remove and store the needle guard, if you used one.
- **Carefully** replace the outer protective cap on the needle, as instructed by your healthcare provider.
- Unscrew the needle and discard it in a proper disposal container. NEVER REUSE A NEEDLE.
- Replace the front cap, then put the GENOTROPIN PEN 12 back in its protective case. Store it in the refrigerator at 36° to 46°F (2° to 8°C) until your next injection.

Your Next Injection

If you already have a drug cartridge in your GENOTROPIN PEN 12, prepare the pen and administer your dose as follows:

- Remove the front cap of the GENOTROPIN PEN 12.
- Remove the paper covering from the back of a new needle.
- Screw the needle onto the metal front part of the pen by turning it clockwise (to the right).
- Remove the outer and inner needle caps.
- Follow the instructions above, starting with step 6.

To Replace the Cartridge

- Press the red release button to reset the GENOTROPIN PEN 12.
- Turn the black/white injection knob counterclockwise (to the left) as far as it will go.
- Unscrew the metal front part and remove the empty cartridge.
- Discard the empty cartridge as instructed by your healthcare provider.
- To insert a new cartridge and prepare the GENOTROPIN PEN 12 for use, follow the instructions above.

Storage

Between uses, store your GENOTROPIN PEN 12 in the refrigerator at 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. Discard the cartridge in your GENOTROPIN PEN 12 within 28 days after reconstitution (mixing of the growth hormone powder with the diluent) even if the cartridge is not empty.

When traveling, keep your GENOTROPIN PEN 12 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.

Caring For Your GENOTROPIN PEN 12

No special maintenance is required. To clean the GENOTROPIN PEN 12, 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 reusable needle guard, wipe it with a damp cloth or alcohol swab.

Disposing of your GENOTROPIN PEN 12

- Your doctor or healthcare provider will instruct you on how to discard your used syringes and needles and other medical waste in an appropriate puncture resistant disposal container such as a 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, syringes, other medical waste, and sharps containers.
- Do not throw needles, syringes, or sharps containers in the household trash without first checking your state and local laws.

COMMON QUESTIONS

How do I tell how much GENOTROPIN is left in the GENOTROPIN PEN 12?

Look at the dose scale imprinted along the side of the window on the metal front part of the pen. The front edge of the gray rubber plunger lines up with the number of milligrams remaining in the cartridge.

What happens when the battery runs low?

The battery in the GENOTROPIN PEN 12 should run for two years. When it begins to run low due to the end of the battery's life, you will see a flashing symbol (=) in the dose display. This means the battery will last about another month. When the battery is dead, the

dose display will show a steady $\equiv \equiv$. A flashing "bt" means the battery is running very low for some other reason and will last for about another month. When the battery is dead, the display will then show a steady "bt".

In either case, call the Pfizer Bridge Program at the toll-free number listed below to exchange your GENOTROPIN PEN 12 for a new one.

If the battery suddenly dies, can the GENOTROPIN PEN 12 still be used?

Yes. Call the Pfizer Bridge Program at the toll-free number listed below for instructions on how to determine the dose without the electronic dose display.

Questions about how to use the GENOTROPIN PEN 12? Call the Pfizer Bridge Program toll-free at (800) 645-1280

Manufactured by: Ypsomed AG Burgdorf, Switzerland

> Distributed by Pharmacia & Upjohn Co Division of Pfizer Inc, NY, NY 10017

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

LAB-0224-7.0 Revised February 2012

Genotropin Pen® 5

Growth Hormone Delivery Device for use with Genotropin® Lyophilized Powder (somatropin [rDNA origin] for injection)

Instructions for Use

Important Note

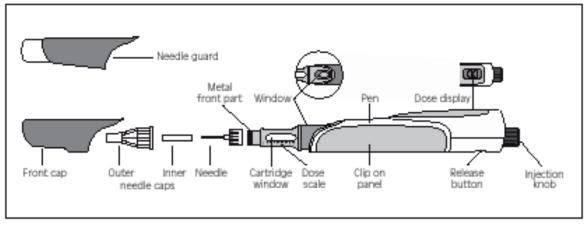
Please read these instructions completely before using the GENOTROPIN PEN 5. If there is anything you do not understand or cannot do, call the toll-free number listed at the end of these instructions. If you have any questions about your dose or your treatment with GENOTROPIN, call your healthcare provider.

GENOTROPIN PEN 5 is a device used to mix and inject doses of GENOTROPIN Lyophilized Powder (somatropin [rDNA origin] for injection). Use this device **only** for administration of GENOTROPIN.

What You Will Need

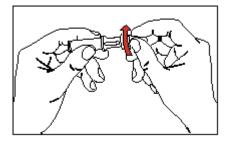
- GENOTROPIN PEN 5
- 5mg two-chamber cartridge of GENOTROPIN
- · Alcohol swab
- 29-gauge, 30-gauge, or 31-gauge Becton Dickinson pen needle
- Proper disposal container for used needles

Components of the GENOTROPIN PEN 5



Before You Begin

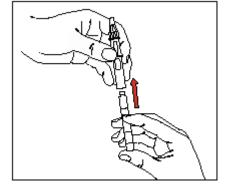
To help prevent infection, always wash your hands with soap and water before preparing or using the GENOTROPIN PEN 5.

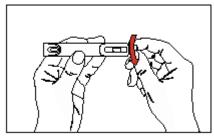


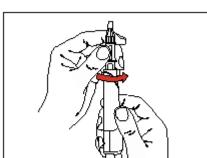
1. Attach the Needle

• Remove the front cap from the GENOTROPIN PEN 5.

- Unscrew the metal front part and detach it from the plastic body of the pen.
- Remove the paper covering from the back of a new needle.
- Screw the needle onto the metal front part by gently turning it clockwise (to the right).







2. Insert the Two-Chamber Cartridge of GENOTROPIN

- Use only the 5 mg cartridge.
- Wipe the metal/rubber tip of the cartridge with an alcohol swab.

• Insert the cartridge into the metal front part of the pen, with the metal/rubber tip towards the needle end. Push the cartridge firmly into place.

3. <u>Prepare the Body of the Pen</u>

- Press the red release button to release the black/white injection knob.
- Turn the black/white injection knob counterclockwise (to the left) as far as it will go.

• Check that the plunger rod is not visible through the window at the top of the plastic body of the pen. DO NOT proceed if the plunger rod is visible, as the medication will not be properly mixed. Instead, press the red release button again to draw back the plunger rod. After the rod is no longer visible through the window, proceed to the next step.

4. Screw the GENOTROPIN PEN 5 Together

• Hold the metal front part upright

• While holding upright, gently screw the metal front part and the plastic body back together. This mixes the diluent in the rear chamber of the cartridge with the growth hormone powder in the front chamber.

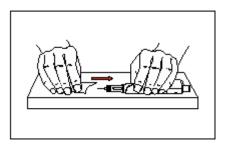
• Gently tip the assembled GENOTROPIN PEN 5 from side to side to help dissolve the powder completely. **DO NOT SHAKE** as that might inactivate the growth hormone.

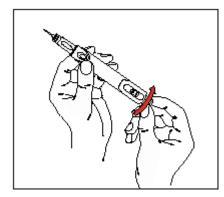
5. Examine Solution and Release Trapped Air

• Look through the cartridge windows in the metal front part of the pen and make sure the drug solution is clear. If you see particles or if the solution is discolored, **DO NOT INJECT IT.** Instead, call the toll-free number listed at the end of these instructions.

- Remove the outer needle cap and save it for later.
- Remove and discard the inner needle cap. Be careful not to touch the exposed needle.
- Remove any trapped air from the solution as follows:
- a) Turn the black/white injection knob clockwise (to the right) one click. This will line up the white mark on the injection knob and the black mark on the body of the pen.
- b) Hold the GENOTROPIN PEN 5 upright and gently tap the metal front part with your finger to move any air bubbles to the top.
- c) Push the black/white injection knob all the way in. You will see a drop of liquid appear at the needle point. Any trapped air has now been released.
- d) If no liquid squirts out, press the red release button and turn the black/white injection knob clockwise (to the right) until it clicks once. Repeat steps b) and c).

• If desired, attach the reusable needle guard over the needle—push until it snaps in place. Again, be careful not to touch the exposed needle. To avoid an accidental needle stick, grip the sides of the needle guard; never push on the end.





6. Dial Your Prescribed Dose

- Press the red release button to reset the device.
- The black/white injection knob will pop out and the dose display window will read 0.0.
- With the dose display activated, turn the black/white injection knob clockwise (to the

right) until your prescribed dose is displayed.

• If you go too far, just turn the knob back the other way until the correct dose is displayed.

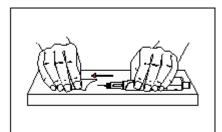
NOTE: If you turn the black/white injection knob backwards beyond zero after a cartridge has been inserted, the pen display will show (--). Just turn the injection knob forward (clockwise) until numbers reappear on the dose display.

• The GENOTROPIN PEN 5 contains a battery for the dose display. 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.** NOTE: Each click of the black/white injection knob equals a one-tenth-of-a milligram dose (or 0.1 mg). One click—or 0.1 mg—is the minimum possible dose per injection; 20 clicks—or 2.0 mg—is the maximum possible dose per injection. If you accidentally dial more than the maximum 2.0 mg dose, some liquid may emerge from the tip. This is normal and will not affect your injection—simply dial back to the correct dose.

7. Inject your GENOTROPIN

Select and prepare an appropriate injection site, as directed by your healthcare provider.
Pinch a fold of skin at the injection site firmly, and push the GENOTROPIN PEN 5 into the skinfold at a 90° angle. Push the pen down as far as possible.

• Push the black/white injection knob until it clicks. Wait at least 5 seconds and then withdraw the GENOTROPIN PEN 5.



- 8. Discard the Needle and Store the GENOTROPIN PEN 5
- Remove and store the needle guard, if you used one.
- Carefully replace the outer protective cap on the needle, as instructed by your healthcare provider.
- Unscrew the needle and discard it in a proper disposal container. NEVER REUSE A NEEDLE.
- Replace the front cap, then put the GENOTROPIN PEN 5 back in its protective case. Store it in the refrigerator at 36°F to 46°F (2°C to 8°C) until your next injection.

Your Next Injection

If you already have a drug cartridge in your GENOTROPIN PEN 5, prepare the pen and administer your dose as follows:

- Remove the front cap of the GENOTROPIN PEN 5.
- Remove the paper covering from the back of a new needle.
- Screw the needle onto the metal front part of the pen by turning it clockwise (to the right).
- Remove the outer and inner needle caps.
- Follow the instructions above, starting with step 6.

To Replace the Cartridge

- Press the red release button to reset the GENOTROPIN PEN 5.
- Turn the black/white injection knob counterclockwise (to the left) as far as it will go.
- Unscrew the metal front part and remove the empty cartridge.
- Discard the empty cartridge as instructed by your healthcare provider.
- To insert a new cartridge and prepare the GENOTROPIN PEN 5 for use, follow the instructions above.

Storage

Between uses, store your GENOTROPIN PEN 5 in the refrigerator at 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. Discard the cartridge in your GENOTROPIN PEN 5 within 28 days after reconstitution (mixing of the growth hormone powder with the liquid) even if the cartridge is not empty.

When traveling, keep your GENOTROPIN PEN 5 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.

Caring For Your GENOTROPIN PEN 5

No special maintenance is required. To clean the GENOTROPIN PEN 5, 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 reusable needle guard, wipe it with a damp cloth or alcohol swab.

Disposing of your GENOTROPIN PEN 5

- Your doctor or healthcare provider will instruct you on how to discard your used syringes and needles and other medical waste in an appropriate puncture resistant disposal container such as a 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, syringes, other medical waste, and sharps containers.
- Do not throw needles, syringes, or sharps containers in the household trash without first checking your state and local laws.

COMMON QUESTIONS

How do I tell how much GENOTROPIN is left in the GENOTROPIN PEN 5?

Look at the dose scale imprinted along the side of the window on the metal front part of the pen. The front edge of the gray rubber plunger lines up with the number of milligrams remaining in the cartridge.

What happens when the battery runs low?

The battery in the GENOTROPIN PEN 5 should run for two years. When it begins to run low due to the end of the battery's life, you will see a flashing symbol (\equiv) in the dose display. This means the battery will last about another month. When the battery is dead, the dose display will show a steady $\equiv \equiv$. A flashing "bt" means the battery is running very low for some other reason and will last for about another month. When the battery is dead, the display will then show a steady "bt".

In either case, call the Pfizer Bridge Program at the toll-free number listed below to exchange your GENOTROPIN PEN 5 for a new one.

If the battery suddenly dies, can the GENOTROPIN PEN 5 still be used?

Yes. Call the Pfizer Bridge Program at the toll-free number listed below for instructions on how to determine the dose without the electronic dose display.

Questions about how to use the GENOTROPIN PEN 5? Call the Pfizer Bridge Program toll-free at (800) 645-1280

Manufactured by: Ypsomed AG Burgdorf, Switzerland

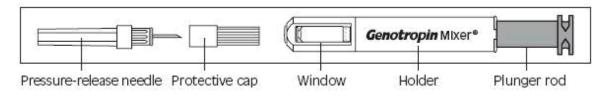


Caution: Federal law restricts this device to sale by or on the order of a physician

LAB-0225-6.0 Revised February 2012

Genotropin Mixer®

Growth Hormone Reconstitution Device

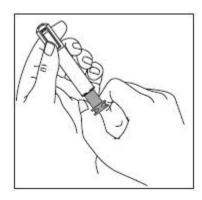


The GENOTROPIN MIXER is a device used to mix growth hormone that is provided in a two-chamber cartridge. Materials needed for injection using the GENOTROPIN MIXER:

- GENOTROPIN MIXER with a pressure-release needle
- One cartridge of GENOTROPIN[®] Lyophilized Powder (somatropin [rDNA origin] for injection), which contains growth hormone and diluent
- Alcohol swab
- Insulin syringe for injection
- Proper disposal container

BEFORE YOU BEGIN...

- First, wash and dry your hands.
- Completely unscrew the dark green **plunger rod** from the light green **holder** of the GENOTROPIN MIXER.
- Remove the two-chamber cartridge of GENOTROPIN from its package.



MIXING GENOTROPIN

- Insert the cartridge into the GENOTROPIN MIXER with the **metallic/rubber tip** of the cartridge facing into the open end of the holder. The metallic/rubber tip of the cartridge should be visible sticking out from the opening at the front of the holder.
- Screw the plunger rod back into the holder. When the two halves are completely screwed together, the growth hormone and the diluent are automatically mixed.

CAUTION: Look in the **window** of the GENOTROPIN MIXER to make sure the growth hormone is completely dissolved. If it is not, gently tip the

GENOTROPIN MIXER from side to side until the liquid is clear. DO NOT SHAKE. The solution should be inspected visually for particulate matter and discoloration prior to administration. If <u>the solution is still cloudy</u>, <u>do not inject it</u>. Remove the cartridge and return it to your supplier. Repeat the procedure using a new cartridge.

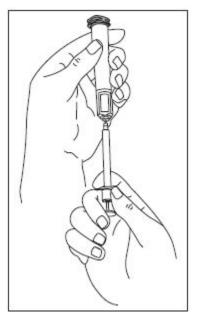
RELEASING PRESSURE

- Disinfect the metallic/rubber tip of the cartridge by wiping it with an alcohol swab.
- Remove the **protective cap** from the **pressure-release needle**. **Do not touch the exposed needle**. With the metallic/rubber tip of the **cartridge pointing upwards**, pierce the rubber tip with the needle.



This will release the excess pressure in the cartridge. Be sure the cartridge is vertical when pierced, to avoid spilling the growth hormone. (This step is only performed the first time you use a new cartridge.)

• Remove the pressure-release needle from the cartridge and discard the needle in a proper disposal container.



INJECTING GENOTROPIN

- Disinfect the metallic/rubber tip of the cartridge by wiping it with an alcohol swab. This must be done each time before the solution is taken from the cartridge.
- Take out an insulin syringe and remove its needle guard. Hold the GENOTROPIN MIXER upside down so that the **metallic/rubber tip is pointing downwards**.
- Insert the needle of the syringe through the rubber tip of the cartridge contained in the GENOTROPIN MIXER, **making sure that the needle tip always stays <u>below</u> the fluid level**. This will minimize air from entering your syringe.
- Holding the side of the syringe body and the end of the syringe plunger rod, pull the plunger of the syringe back slowly to draw out your prescribed dose of growth hormone.
- Still holding the GENOTROPIN MIXER and syringe with its needle pointing upwards, gently tap the side of the syringe to move any air bubbles to the top of the syringe. Then push the syringe's plunger gently to force the air bubbles out of the syringe. Remove the syringe. It is now

ready for your injection.

- Disinfect the area to be injected as directed by your healthcare provider. Pinch the skin firmly between your thumb and forefinger. Hold the syringe close to the needle—like a dart—and push it into the skin at a 45° to 90° angle with a quick, firm action.
- Gently and smoothly inject the growth hormone until the syringe is empty. Withdraw the needle quickly, by pulling it straight out, and apply pressure over the injection site with a dry gauze pad.
- Discard the needle in a proper disposal container.
- The site of the injection should be changed each day.

STORING THE GENOTROPIN MIXER

The GENOTROPIN MIXER with cartridge must be stored in a refrigerator at 36°F to 46°F (2°C to 8°C).

REUSING THE GENOTROPIN MIXER

The cartridge of GENOTROPIN can be reused for up to 28 days after reconstitution. Simply follow the instructions in the "Injecting GENOTROPIN" section. Additional pressure-release needles may be obtained by calling the Pfizer Bridge Program at 1-800-645-1280.

CHANGING THE CARTRIDGE

When the cartridge of GENOTROPIN is empty, you can reuse the GENOTROPIN MIXER with your next cartridge, as follows:

- Unscrew the plunger rod from the GENOTROPIN MIXER.
- Remove and discard the old cartridge.
- Follow the steps beginning with the "Before You Begin" section.

If you have any questions regarding the GENOTROPIN MIXER, contact your healthcare provider or call the Pfizer Bridge Program at 1-800-645-1280.

DISPOSING OF YOUR GENOTROPIN MIXER

- Your doctor or healthcare provider will instruct you on how to discard your used syringes and needles and other medical waste in an appropriate puncture resistant disposal container such as a 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, syringes, other medical waste, and sharps containers.
- Do not throw needles, syringes, or sharps containers in the household trash without first checking your state and local laws.

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



Pharmacia & Upjohn Co Division of Pfizer Inc, NY, NY 10017

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