

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.

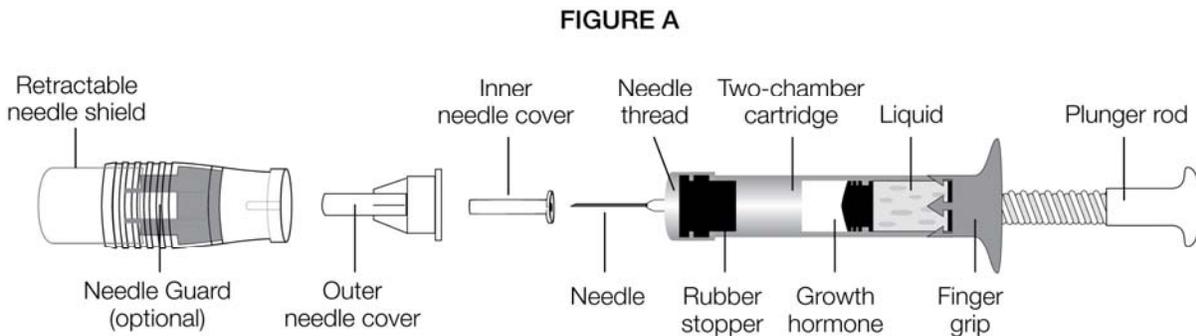
Check your GENOTROPIN MINIQUICK to be sure you have the dose your doctor prescribed.

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.

Using your GENOTROPIN MINIQUICK

Step 1.

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

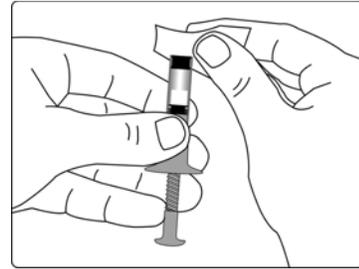
Step 2.

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)

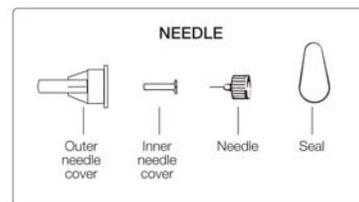
FIGURE B



Step 4.

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

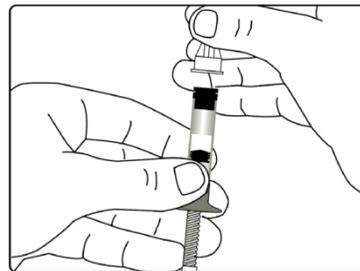
FIGURE C



Step 5.

- 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)

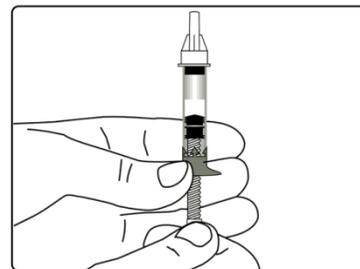
FIGURE D



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.

FIGURE E



- 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.

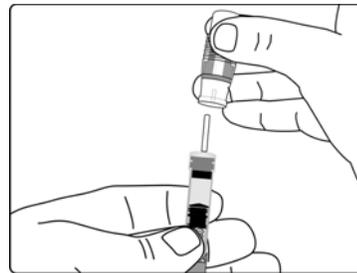
Step 7.

- 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.

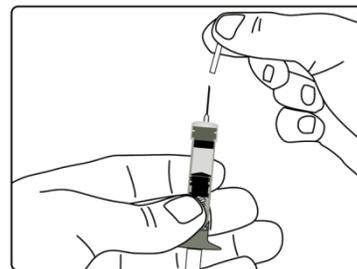
FIGURE F



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.

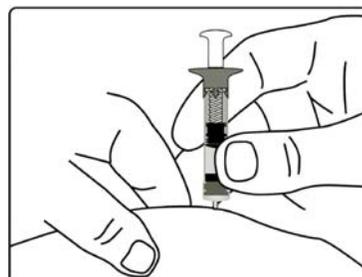
FIGURE G



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.

FIGURE H



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.

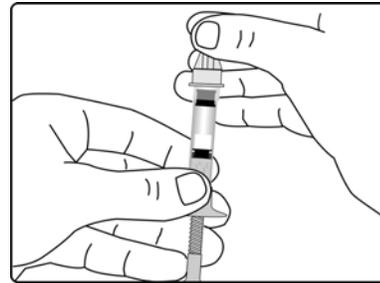
FIGURE I



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 plunger when making the injection (Step 11)? | 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 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



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 **Genotropin MiniQuick®**

Growth Hormone Delivery Device containing Genotropin®
Lyophilized Powder (somatotropin [rDNA origin] for injection)

PHARMACIA