

Genotropin Mixer®

Growth Hormone Reconstitution Device

Instructions for Use

GENOTROPIN Mixer (JEEN-o-tro-pin MIX-er)
Growth Hormone Delivery Device for Mixing Genotropin®
Lyophilized powder (somatropin) for injection

Important Note

Please read these instructions completely before using GENOTROPIN MIXER. 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.

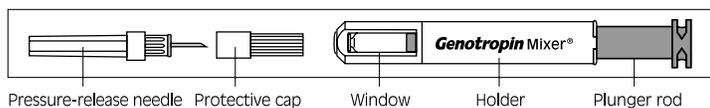
The GENOTROPIN MIXER is a device used to mix growth hormone that is provided in a 2-chamber cartridge of GENOTROPIN.

For each injection you will need:

- GENOTROPIN MIXER
- A pressure-release needle (also called dental needle) (not included).
- One cartridge of GENOTROPIN® Lyophilized Powder (somatropin) for injection, which contains growth hormone powder in one chamber and the liquid in the other (not included).
- Alcohol swab (not included).
- Insulin syringe for injection (not included).
- Proper disposal container (not included).

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

FIGURE A



Storage instructions for your GENOTROPIN MIXER

- Store your GENOTROPIN MIXER (with cartridge) in the refrigerator [36°F to 46°F (2°C to 8°C)]. Always remove the needle before storing.

Using your GENOTROPIN MIXER

Step 1. 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.

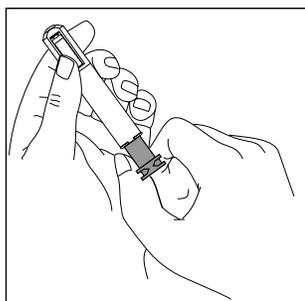
Step 2. Mixing GENOTROPIN

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. (See Figure B)

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 **the solution is still cloudy, do not inject it.** Remove the cartridge and return it to your supplier. Repeat the procedure using a new cartridge.

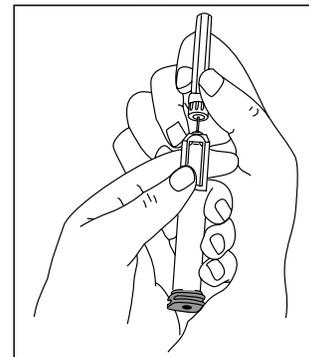
FIGURE B



Step 3. 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.**) (See Figure C)
- Remove the pressure-release needle from the cartridge and discard the needle in a proper disposal container.

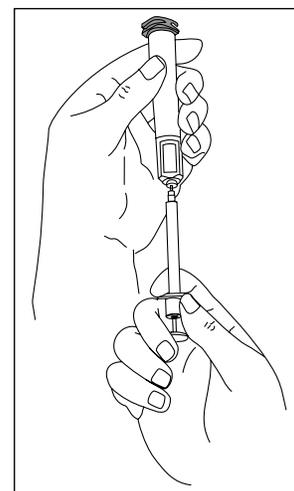
FIGURE C



Step 4. 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 below 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. (See Figure D)
- 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.

FIGURE D



Step 5. 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.

Step 6. 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.

Step 7. Disposing of used needles and cartridges

- 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.

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

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.

Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium



LAB-0228-4.0

Revised September 2016