

GENOTROPIN ZipTip™

Needle-free 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 ZipTip. 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 professional.

GENOTROPIN ZipTip 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 ZipTip Needle-free Delivery Device (reusable reset box, injector, and mixer)
- One disposable sterile ampoule (discarded after each injection)
- One disposable sterile connector (discarded every time the cartridge is changed)
- A two-chamber cartridge of GENOTROPIN (either 5.8 or 13.8 mg, as prescribed for you by your doctor)
- Alcohol swab or disinfectant recommended by your health care professional
- Proper disposal container for used ampoules and connectors

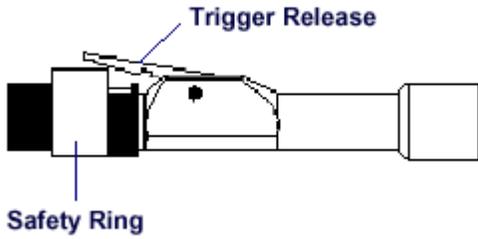
Components of the GENOTROPIN ZipTip

The ZipTip system consists of 3 reusable components: a reset box, an injector, and a mixer. In addition, 2 disposable components are needed for this system: an ampoule and a connector. The diagrams below show the different components.

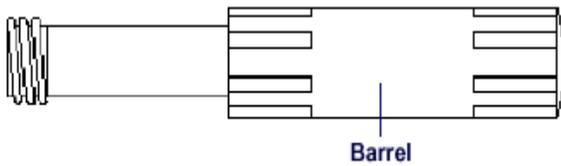
Reusable Reset box



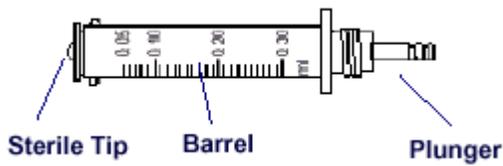
Reusable Injector



Reusable Mixer



Disposable Ampoule



Disposable Connector



Storage

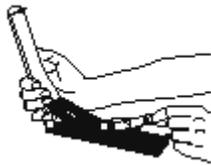
To store GENOTROPIN after reconstitution (mixing the powder and liquid), keep the cartridge inside the mixer, , and store it in the refrigerator for up to 21 days. Do not freeze. Protect from light. If you do not use the reconstituted GENOTROPIN within 21 days, throw it away even if the cartridge is not empty. Do not store reconstituted GENOTROPIN in the ampoule.

When traveling, keep the cartridge with reconstituted GENOTROPIN inside the mixer and carry it in an insulated bag to protect it from heat or freezing. Put the insulated bag in the refrigerator as soon as possible.

To avoid malfunctions, store the GENOTROPIN ZipTip injector and reset box at room temperature (between 59° and 86°F).

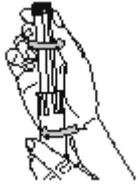
Before You Begin

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



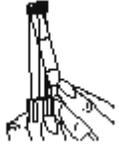
1. Reset the Injector

- Place the reset box on a flat surface with the hinge pointing away from you. Hold the bottom half of the reset box with one hand and using the other hand, lift the lid as far as it will go.
- Make sure that the blue safety ring in the injector is in the “safe” position (pushed as far as it will go toward the injector body). Otherwise the injector will not fit inside the reset box.
- Hold the injector body with the trigger release lever facing up and the black end of the injector pointing away from you and angled downward. Fit the black end of the injector over the tip of the push rod located toward the hinge of the reset box. Set the body of the injector into the box, with the trigger release lever facing up.
- Hold the bottom of the box firmly with one hand, while firmly pushing down on the lid with the other hand to close the box. This resets the injector and prepares it to receive a filled ampoule.
- Open the reset box all the way. Lift the injector and remove it from the reset box. Set the injector on a clean surface.
- If you already have a cartridge with reconstituted GENOTROPIN (the powder and liquid have been mixed) inside the ZipTip mixer, go to Step 6, skipping Steps 2 to 5.



2. **Prepare the Mixer**

- Turn the barrel of the mixer counterclockwise (to the left) as far as it will go.



3. **Insert a Cartridge of GENOTROPIN**

- Take a cartridge of GENOTROPIN out of its packaging.
- Wipe the metal/rubber tip of the cartridge with an alcohol swab.
- Insert the cartridge into the transparent compartment of the mixer, with the powder side of the cartridge pointing up.



4. **Add Connector**

- Take a new connector out of its packaging, being careful not to touch the needle.
- Screw the needle end of the connector onto the tip of the mixer by turning clockwise (to the right) as far as it will go, while holding the transparent part of the mixer. You now have a mixer assembly.



5. **Mix GENOTROPIN**

- Hold the mixer assembly with the connector on top. Slowly turn the barrel of the mixer clockwise (to the right) until the two gray stoppers inside the cartridge come together. Do not turn the barrel any further. The liquid in the rear chamber of the cartridge is now mixed with the growth hormone powder in the front chamber. It is normal to have an air bubble at the top of the front chamber.
- Gently tip the mixer assembly from side to side to help dissolve the powder completely. **Do not shake the assembly.** Shaking may inactivate the growth hormone so it will not work.

Check to make sure the solution is clear, indicating that the growth hormone powder is completely dissolved. 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 this leaflet.



6. Fill an Ampoule

- Do this step just before you are going to inject GENOTROPIN, because you should not store the reconstituted product in the ampoule.
- Lift the protective cap of the connector by pushing up on the lip.
- Take a new ampoule out of its packaging. Do not touch the sterile tip (the end with the black rubber stopper) at any time.
- Push the plunger into the ampoule as far as it will go to remove air from the ampoule.
- Screw the sterile tip of the ampoule into the open end of the connector by turning clockwise (to the right) as far as it will go.

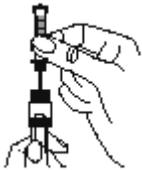


- Turn the mixer assembly so that the ampoule is at the bottom. Slowly, pull down on the ampoule plunger to transfer your dose of GENOTROPIN to the ampoule. Remove any air bubbles that may have been drawn into the ampoule by pushing the plunger up. If necessary, pull down on the plunger again to transfer more GENOTROPIN to the ampoule. The uppermost line of the black rubber on the plunger should be lined up with the number in the scale on the barrel that represents the dose prescribed by your doctor.

Important: If you transfer more liquid than what you need

for your dose, turn the barrel of the mixer counterclockwise (to the left) a few times and then slowly push up the ampoule plunger to return the extra liquid back into the cartridge.

Do not use the product if you can see particles inside the filled ampoule. Instead, remove the ampoule from the mixer assembly and throw away as directed by your health care professional. Check that the remaining solution in the cartridge is clear and does not have particles. If there are no particles in the cartridge, repeat step 6 with a new ampoule. If you can see particles in the cartridge, do not use the medicine and call the toll- free number listed at the end of this leaflet.



- Hold the barrel of the filled ampoule and unscrew it from the connector by turning the ampoule counterclockwise (to the left). Be careful not to touch the sterile tip of the ampoule at any time.
- Close the protective cap on the connector and set aside the mixer assembly.

Important: Keep the connector attached to the mixer until the cartridge of GENOTROPIN is empty. After the cartridge is empty, remove the cartridge and connector and throw them away as instructed by your health care professional. **Never use the same connector for more than one cartridge. Keep the mixer, which is reusable.**

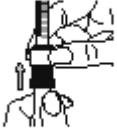
7. **Attach the Filled Ampoule**

Carefully fit the plunger of the filled ampoule inside the black end of the injector. Turn the ampoule clockwise (to the right) as far as it will go. The rim of the ampoule should fit snugly against the end of the injector.

Important: If the plunger of the ampoule does not fit inside the injector, you will need to reset the injector by following the instructions given in Step 1.

Do not place anything other than a filled ampoule into the

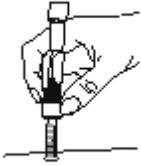
injector.



8. Prepare the Injector

- Slide the blue safety ring toward the ampoule to allow the trigger release lever to work. The injector is now ready for injection.

Important: After the injector is prepared, make sure **never** to point it at yourself or anyone else, especially at the eyes or other sensitive parts of the body. Accidental discharge of the injector can cause injuries.



9. Inject GENOTROPIN

- Check the filled ampoule again to make sure that it contains the dose of GENOTROPIN that was prescribed by your doctor.
- Select and disinfect an appropriate injection site as instructed by your health care professional, allowing the disinfected skin area to dry for a few seconds.
- Press the sterile tip of the ampoule **firmly** against the injection site, applying enough pressure to slightly indent the skin. Make sure that you hold the device straight up and down (perpendicular to the skin), without pinching up or creasing the skin.
- When you are ready, press the trigger release lever to inject the GENOTROPIN. To avoid injuries to the skin, always hold the injector straight up and down and firmly in position while injecting your dose.
- After the injection, continue to hold the injector on the injection site for another 5 seconds. Do not pull or stretch the skin around the injection site.
- Lift the injector from the injection site. Never wipe the injection site with alcohol after the injection. Although it is not necessary, you can blot the skin gently with a clean cotton ball if you wish.
- If some of the dose accidentally squirts into the air or on the skin while you are injecting, do not give yourself another injection that day. Instead, wait until your next scheduled injection. If you have the same problem again, contact your health care professional.



10. Store the ZipTip device

- Slide the blue safety ring away from the ampoule to inactivate the trigger release lever.

Turn the ampoule counterclockwise (to the left) to remove it

from the injector. Throw away the ampoule as directed by your health care professional.

Important: Never reuse an ampoule to avoid infection or injury to yourself, or possible malfunction of the ampoule.

- It is important that you keep the injector clean and free from dust, dirt, and medication residues. Wipe the outside of the injector with a clean damp cloth. Never immerse the injector in any liquid.
- Return the injector to the reset box and close the lid to reset the injector for your next injection. Place the reset box inside the gray carrying pouch and store it at room temperature.
- Never press the trigger release lever with an empty ampoule attached, as this may damage the injector.
- Place the mixer assembly in the refrigerator until your next injection.

Your Next Injection

If the mixer already has a cartridge containing reconstituted GENOTROPIN, prepare your next injection by starting with Step 6 of the instructions.

If the cartridge does not have enough reconstituted GENOTROPIN for a full dose, follow Step 6 of the instructions to transfer the rest of the medicine to the ampoule. Unscrew the ampoule and carefully place it on a clean surface, making sure not to touch the sterile tip. Remove the cartridge and connector from the mixer and throw them away as instructed by your health care professional. Then follow Steps 3 to 5, using a **new** connector and cartridge. Using the partially filled ampoule you had set aside, continue to fill the ampoule with a full dose of GENOTROPIN. Follow steps 7 to 9 to complete the injection.

Questions about how to use the GENOTROPIN ZipTip? Call Pharmacia & Upjohn Company toll-free at (800) 645-1280

Manufactured for:	by:
Pharmacia & Upjohn Company	Rösch AG Medizintechnik
A subsidiary of Pharmacia Corporation	Berlin, Germany
Kalamazoo, MI 49001, USA	

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

NDA 20-280/S-040

Verification Code
Date