

Instructions for Use
ZOMACTON®
(zoh-MACK-ton)
[somatropin]
for Injection

Read the Instructions for Use that come with your ZOMACTON® before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment. Before you use ZOMACTON for the first time, make sure your healthcare provider shows you the right way to use it.

Supplies needed for your ZOMACTON Injection

- **ZOMACTON 5mg (See Figure A)** containing:
 - 1 vial of ZOMACTON 5mg growth hormone in a powder
 - 1 vial of liquid (diluent) containing Bacteriostatic 0.9% Sodium Chloride Injection, USP (5mL). This is used to mix your ZOMACTON 5mg.

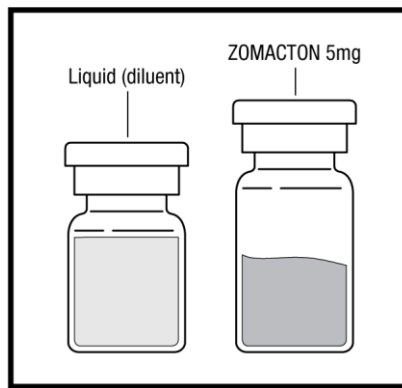


Figure A

or

- **ZOMACTON 10mg (See Figure B)** containing:
 - 1 vial of ZOMACTON 10mg growth hormone in a powder
 - 1 syringe of liquid (diluent) containing Bacteriostatic Water for Injection with 0.33% Metacresol as a preservative (1 mL). This is used to mix your ZOMACTON 10mg.
 - 25 gauge mixing needle

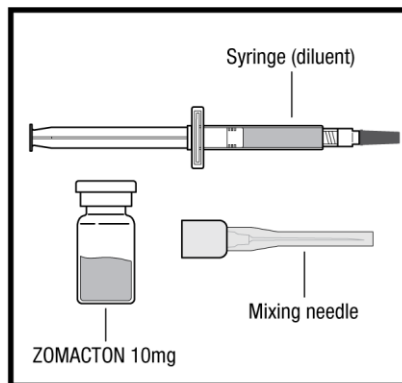


Figure B

The following additional supplies (**See Figure C**) will be needed:

- Syringe and needle for injection. Your healthcare provider will tell you the size of the syringe and needle to use.
- Alcohol swab
- Puncture-resistant container (**See Step 4: Disposing of used syringes, needles, and vials**)

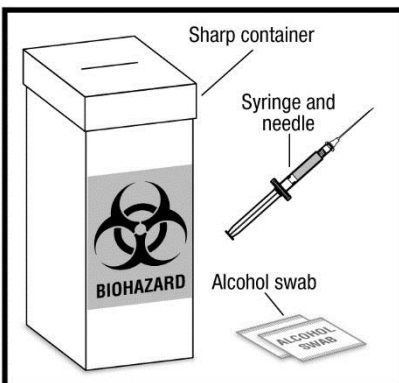


Figure C

Preparing for Your ZOMACTON Injection

- Place the supplies you will need on a clean, flat surface in a well-lit area.
- Wash your hands thoroughly with soap and water.

Important: The liquids are different for the 5mg and 10mg vials.

- **Do not** use the 5mg liquid with the 10mg ZOMACTON.
- **Do not** use the 10mg liquid with the 5mg ZOMACTON.

Preparing ZOMACTON 5mg Liquid for Injection:

- Remove the hard plastic cap from the top of the liquid vial by gently pushing up on the edge of the cap (**See Figure D**). **Do not** remove the rubber stopper.

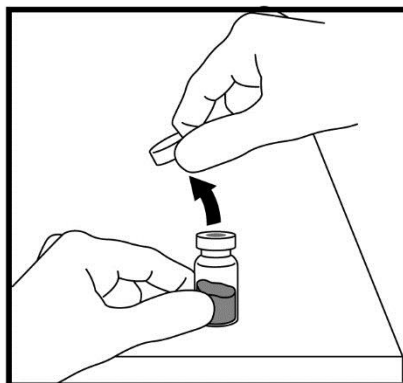


Figure D

- Use an alcohol swab to wipe off the top of the liquid vial (**See Figure E**). After cleaning, **do not** touch the rubber stopper.

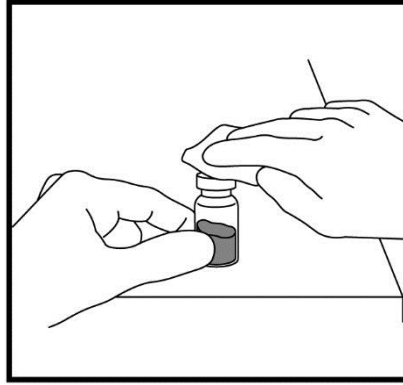


Figure E

- Remove the needle cap from the syringe while making sure you **do not** touch the needle (**See Figure F**). **Do not** throw away the needle cap.

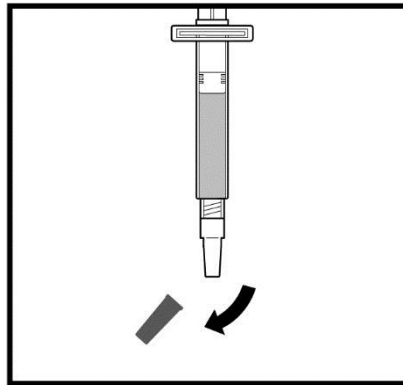


Figure F

- Hold the barrel of the syringe with **1** hand and pull back on the plunger with the other hand until you have drawn up the amount of air that is the same as the amount of liquid your healthcare provider has prescribed (**See Figure G**).

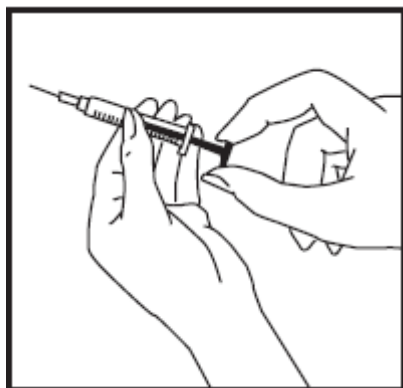


Figure G

- Insert the needle into the liquid vial through the center of the clean rubber stopper. Push down on the plunger until all the air is released into the vial (**See Figure H**).

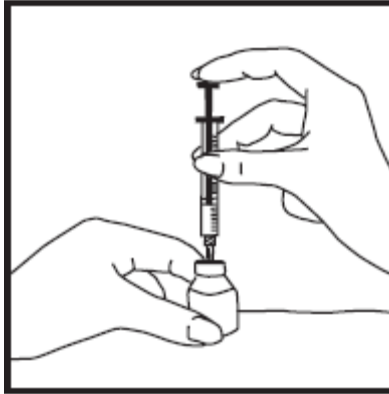


Figure H

- Hold the vial with **1** hand and carefully turn the vial upside down, making sure the syringe needle stays in the vial. **The tip of the needle should be below the surface of the liquid.**
- With your other hand, gently pull back the plunger until the amount of liquid your healthcare provider prescribed is in the syringe (**See Figure I**).



Figure I

When the syringe is correctly filled with the liquid, remove the syringe and needle from the vial and recap the needle.

Preparing ZOMACTON 10mg Liquid for Injection:

- Remove the syringe tip cap from the top of the pre-filled liquid syringe and attach the **25G** mixing needle that comes with your ZOMACTON (**See Figure J**).

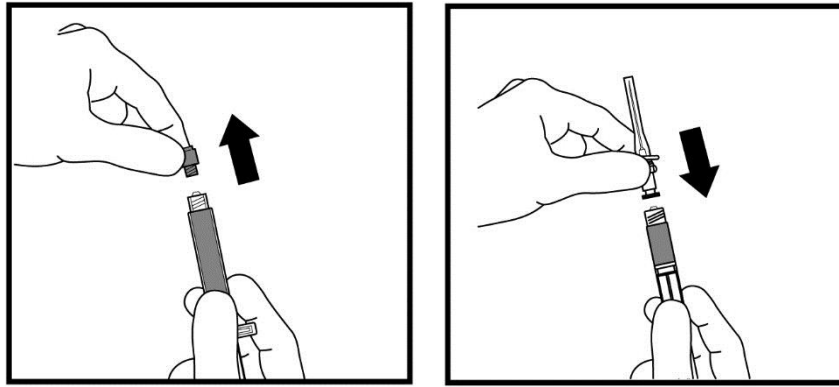


Figure J

Diluting Your ZOMACTON

- **Only** use the liquid that comes with the 5mg ZOMACTON to mix the 5mg growth hormone. **Only** use the liquid that comes with the 10mg ZOMACTON to mix the 10mg growth hormone.
- Remove the hard plastic cap of the growth hormone vial (**See Figure K**).

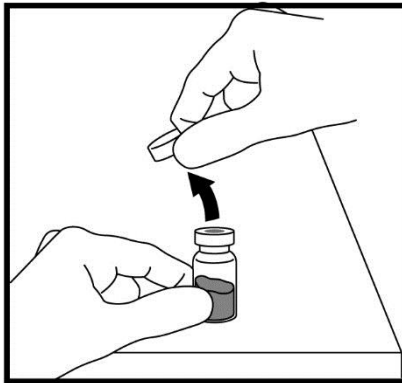


Figure K

- Clean the top of the growth hormone vial with an alcohol swab (**See Figure L**).

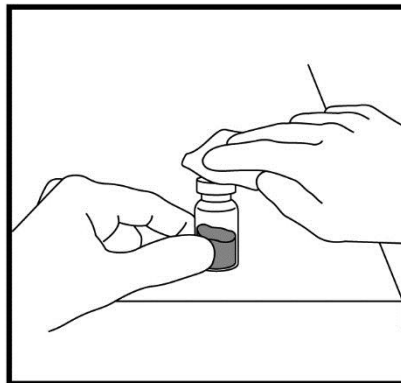


Figure L

- Remove the needle cap from the syringe filled with liquid and insert the needle into the center of the rubber stopper on the growth hormone vial (**See Figure M**).

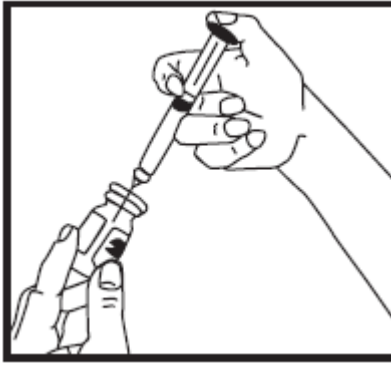


Figure M

- Point the needle toward the side of the vial and slowly push the plunger so that the liquid squirts onto the side of the vial and **not** directly onto the powder.
- When all the liquid is in the growth hormone vial, remove the needle from the vial (**See Figure N**).

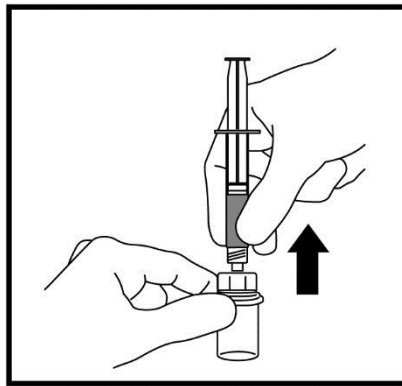


Figure N

- Recap the needle and throw away the syringe.

Mixing ZOMACTON

- Hold the vial between your hands and gently roll it until the mixture is clear. **Do not shake the vial.** Your ZOMACTON is ready for injection.
- Sometimes the vial may need to sit a few seconds before the mixture becomes clear. **Do not** use the mixture in the vial if it remains cloudy or you see particles floating in the mixture. If air bubbles appear, let the growth hormone sit for a while until they disappear.
- Write the date you mixed the growth hormone on the vial label. The **5 mg** vial must be used within **14** days. The 10mg vial must be used within **28** days.
- Store your **mixed** growth hormone and all **unopened vials** of growth hormone in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze.

Step 1: Preparing the Injection

You are now ready for your ZOMACTON injection.

- Wash your hands thoroughly with soap and water.
- Check that the vial of growth hormone you are using is clear and that the date of mixing is within **14** days if you are using ZOMACTON **5mg** or **28** days if you are using ZOMACTON **10mg**.

- Clean the top of the growth hormone vial with an alcohol swab. **Do not** touch the rubber stopper after cleaning (**See Figure O**).

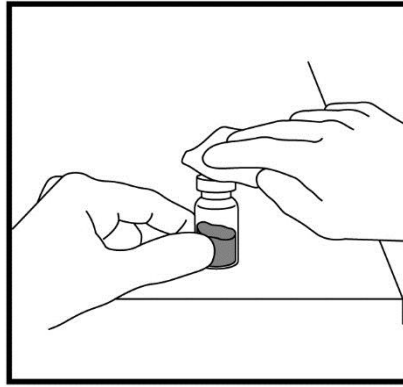


Figure O

- Remove the needle cap from the syringe and insert the needle into the center of the rubber stopper on the growth hormone vial (**See Figure P**).

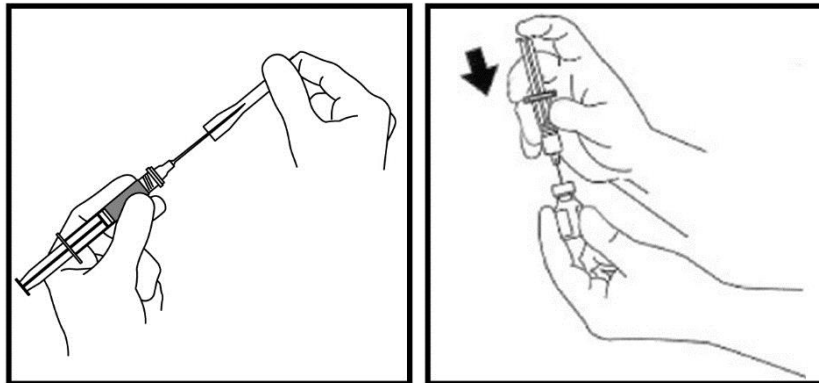


Figure P

- Gently pull back the plunger until the amount of growth hormone solution your healthcare provider has prescribed is in the syringe (**See Figure Q**).

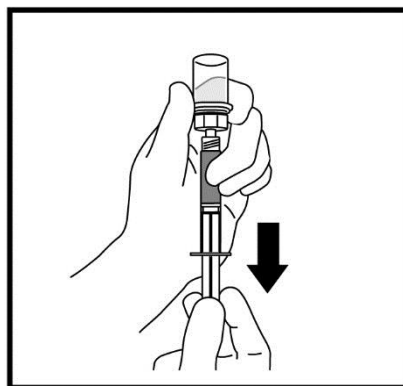


Figure Q

- Remove the needle from the vial when the syringe is correctly filled with the solution (**See Figure R**). Recap the needle.

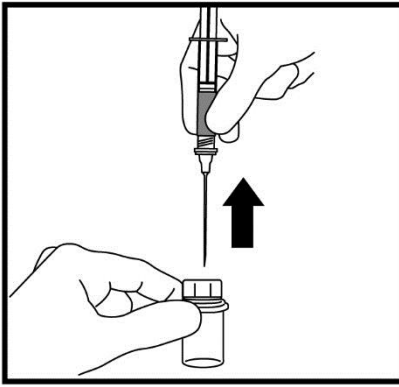


Figure R

Step 2: Choosing an Injection Site

- There are different sites you can use for your injections. These sites should be rotated (**See Figure S**).

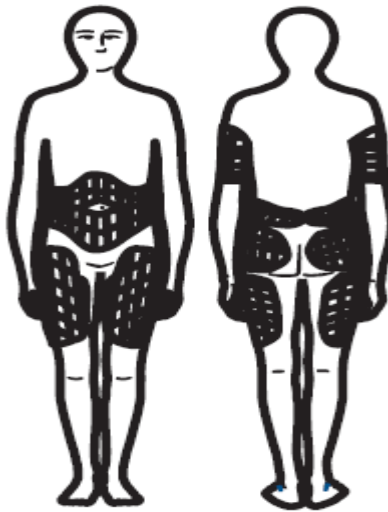


Figure S

If you notice any of the following signs, contact your healthcare provider:

- A lump, bruise or redness at the injection site that does not go away.
- Any sign of infection at the injection site (pus, redness, heat or persistent pain).
- Severe, sharp pain or ache at injection site that does not go away.
- Rash at the injection site.

Step 3: Injecting ZOMACTON

Using a circular motion, clean the injection site with an alcohol swab, starting at the injection site and moving outward about 2 inches. Let the skin air dry.

- Check that the correct dose is in the syringe.
- Remove the needle cap. Hold the syringe like a pencil in 1 hand.
- With your free hand, pinch the skin around the site with the thumb and forefinger of the other hand (**See Figure T**). Quickly insert the needle into the skin at a 45° - 90° angle with a quick, dart-like motion.

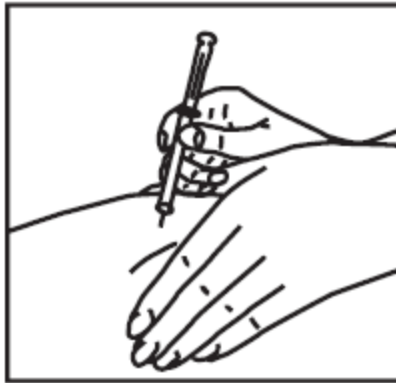


Figure T

- Holding the syringe in place, pull back a little on the plunger and check to see if any blood flows into the syringe (**See Figure U**). If you **see blood in the syringe**, it means that you have entered a blood vessel. **Do not** inject ZOMACTON. Withdraw the needle. Throw away the syringe and needle in a puncture-resistant container. Do not use the same syringe or any of the other supplies that you used for this injection. Repeat the steps to prepare a new syringe for injection. Choose and clean a new injection site.

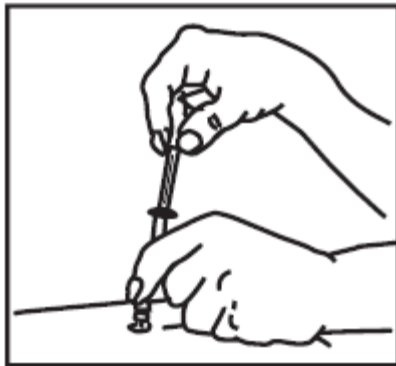


Figure U

- If no blood appears in the syringe, slowly push down plunger all the way until the syringe is completely empty (**See Figure V**).

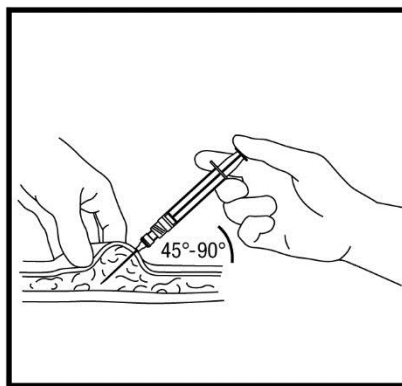


Figure V

- Quickly remove the needle from the skin and apply pressure to the injection site with a dry sterile gauze pad or cotton ball. A drop of blood may appear. Apply a small bandage if needed. Throw away the needle and syringe in your puncture-resistant disposal container.

- Do not share your syringes, needles, or vials with anyone else. You may give them or get an infection from them.

Step 4: Disposing of used syringes, needles, and vials

- To prevent needle-stick injury and spread of infection, do not try to re-cap the needle.
- Place used needles, syringes, and vials in a closeable, puncture-resistant container. You may use a sharps container (such as a red biohazard container), hard plastic container (such as a detergent bottle), or metal container (such as an empty coffee can). Do not use glass or clear plastic containers. Ask your healthcare provider for instructions on the right way to throw away (dispose of) the container. There may be state and local laws about how you should throw away used needles and syringes.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **Do not throw used needles, syringes, or vials in your household trash or recycle.**
- Keep the disposal container, needles, syringes, and vials of ZOMACTON out of reach of children.

This Instructions for Use has been approved by the Food and Drug Administration.

MANUFACTURED FOR:



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Origin Germany

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