INSTRUCTIONS FOR USE

Read this Instructions for Use before you start using GATTEX and each time you get a refill. There may be new information. Your healthcare provider or nurse should show you how to prepare, measure your dose, and give your injection of GATTEX the right way.

If you cannot give yourself the injection:
- ask your healthcare provider or a nurse to help you
- ask someone who has been trained by a healthcare provider or nurse to give your injections.

Important information:
- Before you start, check the “Use By” date on your GATTEX kit. Make sure that the “Use By” date has not passed. Do not use anything in the GATTEX kit after the “Use By” date on the kit.
- Give GATTEX within 3 hours after you mix the powder with the Diluent (Sterile Water for Injection).
- Use the syringes and needles provided in the GATTEX kit.
- Do not use a GATTEX vial more than 1 time, even if there is medicine left in the vial.
- Throw away any unused GATTEX after you give your injection.
- Safely throw away GATTEX vials after use.
- Do not re-use syringes or needles. See “Step 7: Dispose of syringes and needles” for information about how to safely throw away needles and syringes.
- To help avoid needle-stick injuries, do not recap needles.

Gather the supplies you will need to prepare GATTEX and to give your injection (See Figure A).

From your GATTEX kit you will need:
- 5-mg vial of GATTEX with green cap
  Your healthcare provider will tell you how many vials of GATTEX you will need for your injection.
- 2 alcohol swab pads
- Diluent syringe. Your kit has only 1 type of Diluent syringe.
  - With a white snap-off cap or
  - With a gray screw top
- 22G, 1½ inch needle
- Plastic dosing syringe with needle attached
- A sharps disposal container. See “Step 7: Dispose of needles and syringes.” (not included in the GATTEX kit)

You may also need an adhesive bandage (not included in your GATTEX kit).
**STEP 1** Prepare the injection.

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and water.

**STEP 2** Preparing the Diluent syringe.

- Put the Diluent syringe (See Figure B1) and 22G, 1½ inch needle in front of you on your work surface.
- Hold the Diluent syringe by the barrel (See Figure R). Empty all the Diluent into the GATTEX vial.
- Gently tap the barrel of the Diluent syringe with a finger (See Figure E).
- Make sure all the Diluent has gone from the syringe into the vial. (See Figure F).
- When the syringe is empty, quickly pull the needle out of your skin. Let the vial sit for about 2 minutes.
- Slowly pull back the plunger of the dosing syringe to match your prescribed dose (See Figure O).
- Hold the vial with 1 hand. Slowly pull back the plunger of the dosing syringe with your other hand. Do not inject into areas where the skin is tender, bruised, red, or hard.
- Withdraw any unused GATTEX that has been mixed, even if there is medicine left in the vial.
- Do not store any GATTEX you have mixed.

**STEP 3** Mix GATTEX powder with Diluent.

- Remove the green cap from the GATTEX vial. Throw away the green cap.
- Find the gray rubber seal on top of the vial (See Figure E).
- Remove the plastic dosing syringe from the package to peel back the plastic cover (See Figure K).
- Use an alcohol swab pad to clean the gray rubber seal (See Figure F).
- Do not touch the gray rubber seal after you clean it.
- Pick up the Diluent syringe with the needle attached.
- Remove the plastic cap that covers the needle (See Figure Q).
- Throw the cap away.
- Hold the vial between thumb and index finger (See Figure H). Be careful not to touch the gray rubber seal.
- Push the needle through the center of the gray rubber seal.
- Gently push down on the plunger of the Diluent syringe. Empty all the Diluent into the GATTEX vial.
- Leave the needle and Diluent syringe in place.

**STEP 4** Check the mixed GATTEX.

- After 2 minutes, look at the vial of GATTEX. The liquid in the vial should be clear and colorless to pale yellow, and should not have any particles in it.
- If there is any powder in the vial that did not dissolve, gently roll the vial for about 15 seconds (See Figure J).
- Do not shake the vial.
- Check the vial again for anything that did not dissolve.
- Do not use the vial if there is anything in it that did not dissolve. Start from the beginning of this Instructions for Use for preparing a new vial. Use a new GATTEX vial, new Diluent syringe, and a new needle.

**STEP 5** Draw up your dose of GATTEX.

- Remove the plastic cap from the dosing syringe (See Figure L).
- Do not touch the needle or allow it to touch anything.
- Carefully pull back on the plunger to the line that matches the dose prescribed by your healthcare provider.
- Use 1 hand to hold the vial steady. Use your other hand to insert the needle straight down into the middle of the gray rubber seal on the GATTEX vial (See Figure M). You may feel some resistance as the needle passes through the rubber seal.
- Gently push down the plunger until all of the air has gone from the syringe into the vial.
- Hold the GATTEX vial with 1 hand while you slowly push down the plunger until the syringe is empty (See Figure V).
- When the vial is empty, quickly pull the needle out of your skin. There may be a little bleeding at the injection site. Apply an adhesive bandage to the injection site if needed.

**STEP 6** Inject GATTEX.

- Clean the skin where you plan to give the injection with a new alcohol swab pad. Do not touch this area again before giving the injection.
- Use a new GATTEX vial, new Diluent syringe, and a new needle. If you have the Diluent syringe with the white snap-off cap: Snap off the cap and 22G, 1½ inch needle attached.
- Choose an injection site on your stomach area (abdomen), thighs, or upper arms. Choose a different site to give the injection each day.
- Do not inject into areas where the skin is tender, bruised, red, or hard. 
- Gently tap the barrel of the Diluent syringe with a finger (See Figure H). Be careful not to touch the gray rubber seal.
- Push the needle down through the center of the gray rubber seal.
- Slowly pull back the plunger to draw up the right dose of GATTEX into the syringe.
- Hold the Diluent syringe and needle from the GATTEX vial (See Figure Q). Do not touch the needle or allow it to touch anything.

**STEP 7** Dispose of syringes and needles.

- Do not re-use a syringe or needle.
- To help avoid needle-stick injuries, do not recap a needle.
- Put your needles and syringes in an FDA-cleared sharps disposal container right after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharp items 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 local or state laws about how to throw away syringes and needles. 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/cancer sharps disposal.
- Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
- Throw away the GATTEX vial into the container where you put the syringes and needles. If you have any questions, talk to your healthcare provider or pharmacist.

How should I store GATTEX?

- Store GATTEX powder at room temperature up to 77°F (25°C).
- Do not freeze GATTEX.
- Use GATTEX powder by the expiration date on the “Use By” sticker on the kit.
- Use GATTEX within 3 hours after mixing it.
- Throw away any unused GATTEX that has been mixed, even if there is medicine left in the vial.
- Do not store any GATTEX you have mixed.

Keep GATTEX and all medicines out of the reach of children.

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

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