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.

Self-administration is not recommended in pediatric patients. In pediatric patients, GATTEX should be injected by:
- a healthcare provider or nurse, or
- a parent or adult caregiver who has been trained by a healthcare provider or nurse to give injections of GATTEX to pediatric patients

Important information:
- Use of the GATTEX 5 mg kit is not recommended in pediatric patients weighing less than 22 pounds (10 kg).
- 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.
- Safely throw away GATTEX vials after you give your injection.
- 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 with a white snap-off cap
- Needle for reconstitution (22G, 1½ inch)
- Plastic dosing syringe (1 mL) with needle attached (26G, 5/8 inch)
- A sharps disposal container (not included in the GATTEX kit). See “Step 7: Dispose of needles and syringes.”

You may also need an adhesive bandage (not included in your GATTEX kit).

For Important Safety Information, click here for full Prescribing Information and Medication Guide, and discuss any questions with your doctor.
**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. Snap off the white cap (bend pointer finger (45-degree angle with a quick, “dart-like” motion). Be careful not to touch the gray rubber seal.
- Push the open end of the needle onto the needle cap from the dosing syringe (See Figure F).
- Use your other hand to hold the syringe. Insert the full length of the needle into the skin at a 45-degree angle with a quick, “dart-like” motion (See Figure U).
- Use 1 hand to gently pinch up a fold of skin with your other hand.
- Use 1 hand to gently pinch up a fold of skin with your other hand (See Figure T).
- Hold the GATTEX vial with 1 hand.
- Slowly push back the plunger of the dosing syringe with your other hand.
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose (See Figure O).
- Keep the syringe and needle in the vial.
- You may see some bubbles inside the vial when the syringe is filled. This is normal. With the needle still in the vial, gently tap the side of the syringe with a finger to make any air bubbles rise to the top (See Figure P).
- Slowly push the plunger up until all air bubbles are out of the syringe. Make sure the tip of the needle is in the fluid. Slowly pull back the plunger to draw up the right dose of GATTEX into the syringe.
- Remove the dosing syringe and needle from the vial (See Figure Q). Do not touch the needle or allow it to touch anything.

**STEP 3** Mix GATTEX powder with Diluent.
- Gently tap the barrel of the Diluent syringe with a finger (See Figure I).
- Make sure all the Diluent has gone into the GATTEX vial.
- Remove the Diluent syringe and needle from the GATTEX vial. Let the vial sit for about 30 seconds.
- Do not put the needle cap back on the needle.
- Throw away (dispose of) the Diluent syringe and needle in your sharps disposal container.
- After 30 seconds, place the vial between the palms of your hands. Gently roll the vial for about 15 seconds (See Figure J).
- Do not shake the vial.
- Do not touch the gray seal. If you do, clean it again with a new alcohol pad.
- Let the vial stand on your work surface for about 2 minutes.

**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 between your hands for 15 seconds more.
- 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 to prepare a new vial. Use a new GATTEX vial, new Diluent syringe, and a new needle cap from the dosing syringe (See Figure L).
- Remove the needle cap from the dosing syringe (See Figure L).
- Throw the needle cap away. 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.
- Turn the GATTEX vial and syringe upside down (See Figure N).
- Hold the GATTEX vial with 1 hand.
- Slowly push back the plunger of the dosing syringe with your other hand.
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose (See Figure O).
- Keep the syringe and needle in the vial.
- You may see some bubbles inside the vial when the syringe is filled. This is normal. With the needle still in the vial, gently tap the side of the syringe with a finger to make any air bubbles rise to the top (See Figure P).
- Slowly push the plunger up until all air bubbles are out of the syringe. Make sure the tip of the needle is in the fluid. Slowly pull back the plunger to draw up the right dose of GATTEX into the syringe.
- Remove the dosing syringe and needle from the vial (See Figure Q). Do not touch the needle or allow it to touch anything.

**STEP 5** Draw up your dose of GATTEX.
- Remove the plastic dosing syringe from the package. Use the fold in the package to peel back the plastic cover (See Figure C). Leave the plastic cap on the needle.
- Push the open end of the needle onto the end of the Diluent syringe (See Figure D). Twist the needle clockwise (to the right) until it stops turning.
- When the needle is tightly in place, put the Diluent syringe and needle on your work surface.

**STEP 6** Inject GATTEX.
- 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. (See Figure R and Figure S).

**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 away 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/safesharpsdisposal.
- 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.

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**How should I store GATTEX?**

- Store GATTEX powder at room temperature up to 77°F (25°C).
- Do not freeze GATTEX.
- Use the 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.

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**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. Manufactured for: Shire NPS Pharmaceuticals, Inc., a Takeda company 300 Shire Way Lexington, MA 02421 USA 1-800-828-2088 Revised: 05/2019 GATTEX® is a registered trademark of Shire-NPS Pharmaceuticals, Inc., a Takeda company. Copyright © 2019 Takeda Pharmaceutical Company Limited. All rights reserved.