

Glatiramer Acetate Injection
20 mg/1.0 mL or 20 mg/0.5 mL
in a Prefilled Syringe
For Investigational Use Only

Read this information carefully before you use glatiramer acetate.

What are the possible side effects of glatiramer acetate?

- **Call your doctor right away if you develop any of the following symptoms: hives, skin rash with irritation, dizziness, sweating, chest pain, trouble breathing, or severe pain at the injection site.** Do not give yourself any more injections until your doctor tells you to begin again.
- The most common side effects of glatiramer acetate are redness, pain, swelling, itching, or a lump at the injection site. These reactions are usually mild and seldom require medical care.
- Some patients report a short-term reaction right after injecting glatiramer acetate. This reaction can involve flushing (feeling of warmth and/or redness), chest tightness or pain with heart palpitations, anxiety, and trouble breathing. These symptoms generally appear within minutes after an injection, last a few minutes, and then go away by themselves without further problems.
- A permanent depression under the skin at the injection site may occur, due to a local destruction of fat tissue.
- **If symptoms become severe, call the emergency phone number in your area.** Do not give yourself any more injections until your doctor tells you to begin again.

These are not all the possible side effects of glatiramer acetate. For a complete list, ask your doctor or pharmacist. Tell your doctor about any side effects you have while taking glatiramer acetate.

How should I store glatiramer acetate prefilled syringes?

Keep the glatiramer acetate prefilled syringe carton in the refrigerator 36-46° F (2°-8°C), out of the reach of children. **Do not freeze** glatiramer acetate. If glatiramer acetate prefilled syringe freezes, do not use, return to the clinic. Glatiramer acetate is light sensitive. Protect it from light when not injecting. Do not use the prefilled syringe if the solution contains particles or is cloudy.

How do I inject Glatiramer Acetate?

There are 3 basic steps for injecting glatiramer acetate prefilled syringes:

1. Gather the materials.
2. Choose the injection site.
3. Give yourself the injection.

Step 1: Gather the materials

1. First, place each of the items you will need on a clean, flat surface in a well-lit area:
 - 1 blister pack with glatiramer acetate prefilled syringe. Remove only 1 blister pack from the glatiramer acetate prefilled syringe carton. Keep all unused syringes in the prefilled syringe carton and store them in the refrigerator.
 - Alcohol prep (wipe)
 - dry cotton ball (not supplied)
2. Let the blister pack with the syringe inside to warm up to room temperature for 20 minutes.
3. To prevent infection, wash your hands. Do not touch your hair or skin after washing.
4. There may be small air bubbles in the syringe. To avoid loss of medicine when using glatiramer acetate prefilled syringes, do not expel (or do not attempt to expel) air bubbles from the syringe before injecting the medicine.



Manufactured by: Teva Pharmaceutical Industries Ltd., 64 H'ashikma st., Kfar Sava 44102, Israel

Step 2: Choose the injection site

There are 7 possible injection areas on your body: arms, thighs, hips and lower stomach area (abdomen) (See Figure 1).

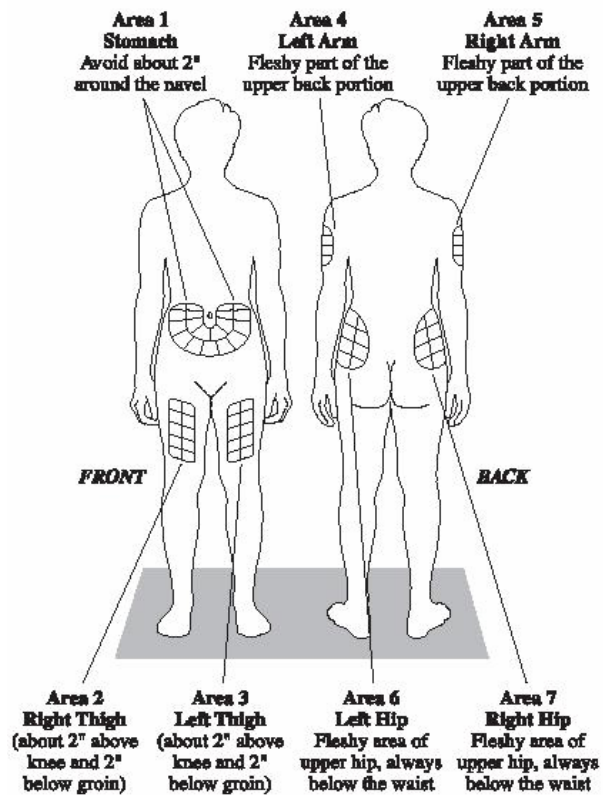


Figure 1

Each day, pick a different injection area from one of the 7 areas.

Do not inject in the same area more than once a week.

Within each injection area there are multiple injection sites. Have a plan for rotating your injection sites. Keep a record of your injection sites, so you know where you have injected.

There are some sites in your body that may be hard to reach for self-injection (like the back of your arm), and you may need help.

Do not inject in sites where skin depression has occurred, because further injections in these sites may make the depression deeper.

Step 3: Give yourself the injection

1. Remove the syringe from its protective blister pack by peeling back the paper label. Before use, look at the liquid in the syringe. If it is cloudy or contains any particles, **do not** use it. If the liquid is clear, place the syringe on the clean, flat surface.
2. Choose an injection site on your body. Clean the injection site with a new alcohol prep and let the site air dry to reduce stinging.
3. Pick up the syringe as you would a pencil. Remove the needle shield from the needle.
4. With your other hand, pinch about a 2-inch fold of skin between your thumb and index finger (See Figure 2).
5. Insert the needle at a 90 degree angle (straight in), resting the heel of your hand against your body. When the needle is all the way in, release the fold of skin (See Figure 3).



Figure 2



Figure 3

6. To inject the medicine, hold the syringe steady and push down the plunger.
7. When you have injected all the medicine, pull the needle straight out.
8. Press a dry cotton ball on the injection site for a few seconds. **Do not rub the injection site.**
9. Throw away the syringe in a safe hard-walled plastic container.

What is the proper use and disposal of prefilled syringes?

Each prefilled syringe should be used for only 1 injection. Throw away all used prefilled syringes in a hard-walled plastic container, such as an empty liquid laundry detergent bottle. Keep the container closed tightly and out of the reach of children. When the container is full, check with your doctor, pharmacist, or nurse about proper disposal, as laws vary from state to state.