

INSTRUCTIONS FOR USE

PURIFIED CORTROPHIN GEL (Repository Corticotropin Injection USP)

40 USP units/0.5 mL and 80 USP units/mL
Single-dose prefilled syringe

For Subcutaneous Use Only

This Instructions for Use contains information on how to prepare and inject Purified Cortrophin Gel prefilled syringe.

Your healthcare provider should show you how to prepare and inject Purified Cortrophin Gel the right way before you inject it for the first time. Do not try to inject yourself until you have been shown the right way to give your injections by your healthcare provider.

Purified Cortrophin Gel prefilled syringe (see **Figure A**).

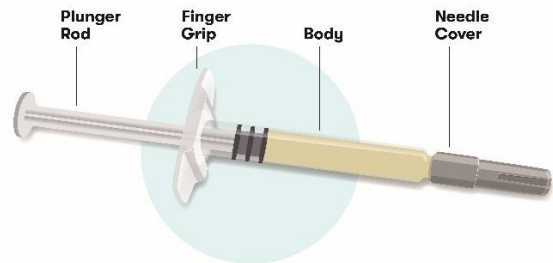


Figure A

Important information you need to know before injecting Purified Cortrophin Gel

- Read all of this Instructions for Use carefully before using the Purified Cortrophin Gel prefilled syringe.
- Purified Cortrophin Gel is given as an injection directly under the skin as directed by your healthcare provider.
 - **Do not** inject it into a vein or take by mouth.
- Inject Purified Cortrophin Gel exactly as your healthcare provider tells you. Your healthcare provider will tell you where to give the injection, how much to give, how often, and when to give it.
 - **You may need more than 1 injection based on your prescribed dose.**
- Do not use Purified Cortrophin Gel until your healthcare provider has shown you how to give the injection.
- Do not use if the tamper evident seal is torn, loose, or not present.
- Do not use the Purified Cortrophin Gel prefilled syringe if it has been dropped on a hard surface or damaged.

1. Collect your supplies

- Use a clean, flat surface, such as a table.
- You will need (see **Figure B**):
 - 1 Purified Cortrophin Gel prefilled syringe (see **Figure A**)
 - 1 alcohol pad
 - 1 cotton ball or gauze pad
 - 1 bandage (if needed)
 - Sharps container for throwing away used syringes and needles (see “**Disposing of your used prefilled syringes and needles**”)



Figure B

2. Preparing the prefilled syringe

- Remove the carton from the refrigerator and place on a clean surface for **45 minutes** to let the prefilled syringe warm up to room temperature 68°F to 77°F (20°C to 25°C) (see **Figure C**).
 - Purified Cortrophin Gel will be a solid gel when refrigerated and it needs to be warmed to a liquid gel before injecting.
 - Remove the prefilled syringe by the syringe body only. **Do not** remove the prefilled syringe by the plunger rod or needle cover.
 - **Do not** remove the needle cover while allowing the prefilled syringe to reach room temperature.
 - **Do not** warm the prefilled syringe in any other way. For example, do not microwave or heat on the stove.
 - **Do not** use the prefilled syringe if the gel in the syringe still appears to be solid.



Figure C

3. Check your medicine

- Check the expiration date on the syringe label (see **Figure D**). **Do not** use if expiration date has passed.
- Make sure that you have the right dose as prescribed to you by your healthcare provider. Your dose may require more than 1 injection.
- Check that the liquid gel in the syringe is light amber (yellow) in color. **Do not** use if the gel appears cloudy or has particles in it. Throw it away (discard) and get a new syringe.
- It is ready to be used when the medicine is a liquid gel and not a solid gel.

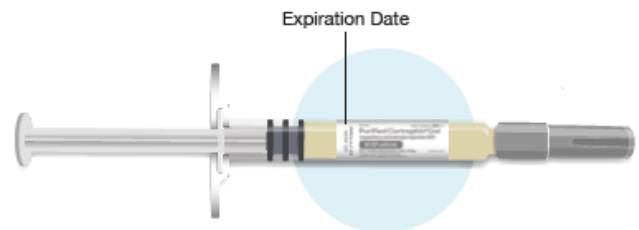


Figure D

4. Selecting an injection site

- Wash your hands well and dry with a clean towel.
- **Choose an injection site** on the stomach (abdomen) area or upper thigh (see **Figure E**).
 - **Do not** inject within 2 inches of the belly button (navel).
- **Do not** inject in areas where the skin is red, swollen, irritated, inflamed, tender, bruised, scaly, hard, or has scars or stretch marks.

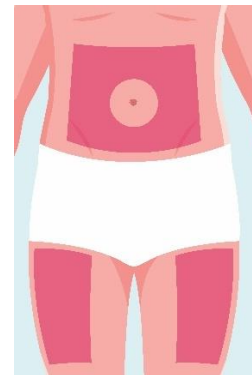


Figure E

- **If someone else is giving you the injection**, it can also be injected in the side and back of the upper arm (see **Figure F**).

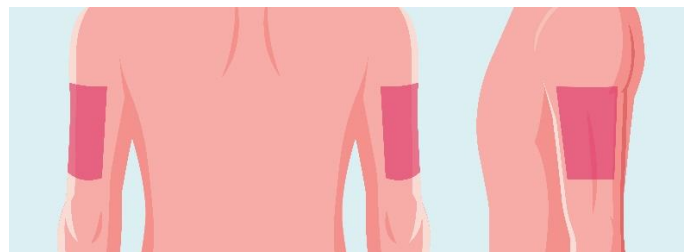


Figure F

5. Injecting Purified Cortrophin Gel

- Clean the injection site with an alcohol pad (see **Figure G**). Allow to air dry.

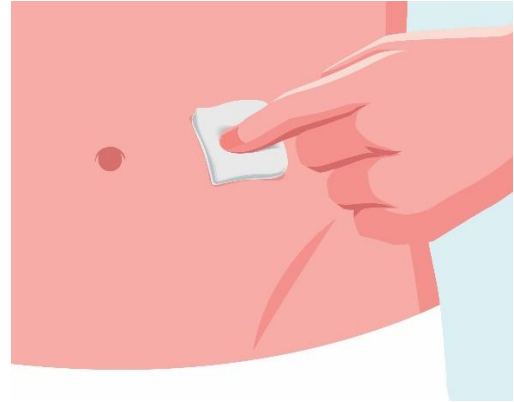


Figure G

- Hold the syringe by the body with one hand.
 - **Do not** move or pull back on the plunger.
- Remove the needle cover with the other hand and throw it away (discard) (see **Figure H**).
 - **Do not** touch the needle.
 - **Do not** recap the needle.
 - You may see a drop of liquid at the end of the needle. This is normal.

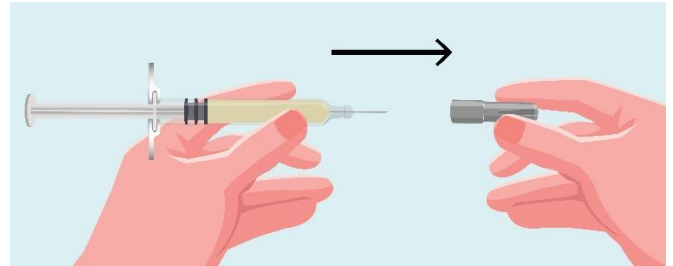


Figure H

- With one hand, gently pinch the area of the cleaned skin and hold it firmly (see **Figure I**).
- Insert the needle into the pinched skin at a 45-degree angle (see **Figure I**).
- Release the pinched skin and slowly push down the plunger until all the medicine has been injected.
- Pull the needle out of the skin while keeping the syringe at the same angle.

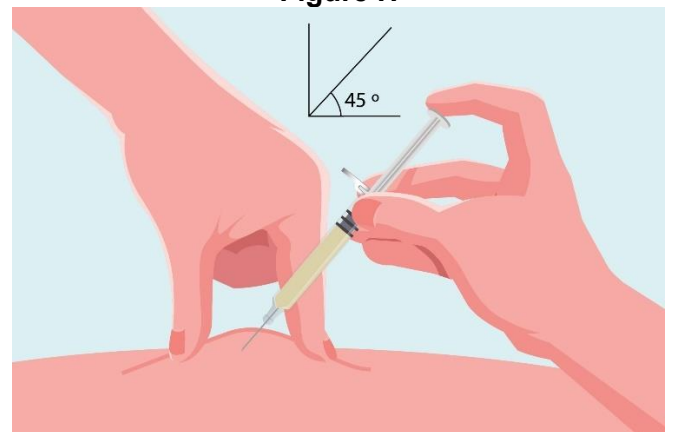


Figure I

- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad over the injection site. Do not rub the injection site.
- If needed, you may cover the injection site with a bandage (see **Figure J**).

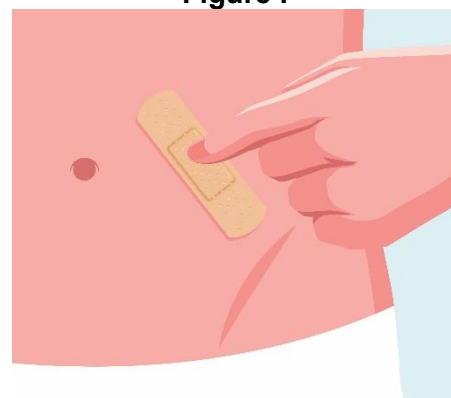


Figure J

6. Disposing of your used prefilled syringes and needles

- Throw away (discard) the prefilled syringe into an FDA cleared sharps container right away after use (see **Figure K**). **Do not** throw away (dispose of) your used needles and syringe in your household trash.



Figure K

- If you do not have an 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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Storing Purified Cortrophin Gel prefilled syringes

- Store Purified Cortrophin Gel prefilled syringes in the carton provided in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Purified Cortrophin Gel prefilled syringes may be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 24 hours.
- Keep Purified Cortrophin Gel prefilled syringes in the carton until ready to use.
- Throw away (discard) Purified Cortrophin Gel prefilled syringes right away after use or by the expiration date stamped on the syringe.
- **Keep Purified Cortrophin Gel and all medicines out of the reach of children.**

Distributed by: ANI Pharmaceuticals, Inc., Baudette, MN 56623



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

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