

INSTRUCTIONS FOR USE

Important Information You Need to Know Before Injecting PTG-300

Storing PTG-300 Before Use

Rusfertide (PTG-300) for injection, for subcutaneous use

This "Instructions for Use" contains information on how to prepare and inject PTG-300.

If you have questions about how to prepare and/or inject PTG-300, please contact your Clinical Site.

- Read all the below instructions for use before beginning the preparation and injection of PTG-300.
- Use only the supplies provided with the drug kit.
- **Do not** use if the kit is expired or if any of the supplies are opened, damaged or missing. Contact the Clinical Site.
- Remove the kit from the refrigerator at least 15 minutes before you start preparing to allow it to warm to room temperature.
- You will need a Sharps Container (provided by Clinical Site) in addition to your drug kit, each time you inject.
- **Do not** touch the gray rubber stopper on the top of the vials.
- **Do not** let the syringe tip or needle touch your hands or any surface.
- For subcutaneous injection only (inject directly into the fatty layer just under the skin).
- Refer to the Disposing of Rusfertide (PTG-300) section on how to properly dispose of or return supplies from the kit, including safe handling.

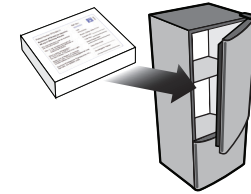


Figure A

- Store the PTG-300 kit in the refrigerator (2° to 8°C / 36° to 46°F) (Figure A).
- **Do not** freeze.
- **Keep out of reach of children.**

Step 1: Getting Started

1.1

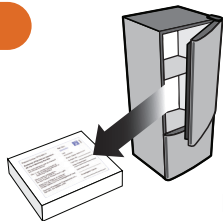


Figure B

- Remove the kit from the refrigerator at least 15 minutes before you start preparing the dose (Figure B).
- Place on a clean flat surface and **let sit for at least 15 minutes** to allow it to warm to room temperature.

1.2



Figure C

- Wash hands with soap and water (Figure C).

1.3

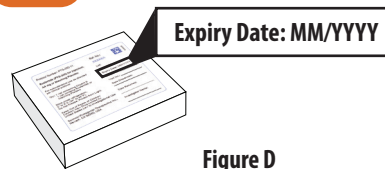


Figure D

- Check the **expiration date** on the outside of the kit's carton (Figure D).
 - Check if the supplies have been **opened, damaged or missing**.
- Do not** use if the kit is expired or if any of the supplies are opened, damaged or missing. Contact the Clinical Site.

1.4

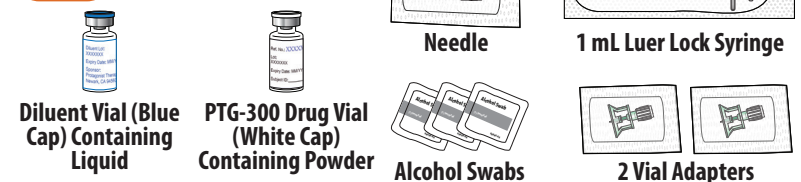


Figure E

- Remove items from kit (Figure E) and place on clean flat surface.

Note: In addition to the items that come in the kit, you will also need a Sharps Container (Figure F).



Sharps Container
(Provided Separately)

Figure F

Step 2: Preparing Diluent Syringe

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2.1

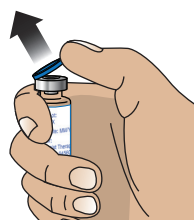


Figure G

- Remove the blue cap from the diluent vial (Figure G).

2.2



Figure H

- Clean gray rubber stopper on top of diluent vial with an alcohol swab (Figure H). Dispose of used swab.
- Do not** touch the gray rubber stopper on the top of the vial with your hand after cleaning.

2.3

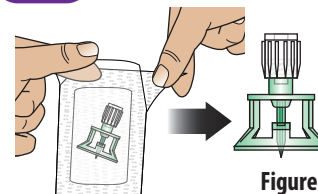


Figure I

- Remove one vial adapter from its package (Figure I).
- Do not** touch adapter spike.

2.4

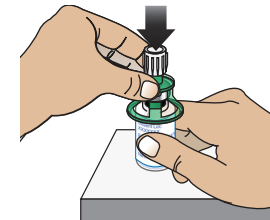


Figure J

- Attach the vial adapter to the diluent vial by holding the vial on a clean flat surface and pushing the vial adapter straight down onto the top of vial (Figure J).
- Note:** The spike on the vial adapter should punch through the gray rubber stopper.

Step 2: Preparing Diluent Syringe (Continued)

2.5

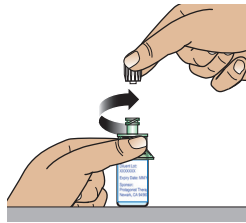


Figure K

- Remove the clear vial adapter cap by holding the vial adapter with one hand, and with the other, unscrew the cap counter-clockwise/to the left until it lifts away (Figure K). Discard the vial adapter cap.

Do not touch the vial adapter tip.

2.6

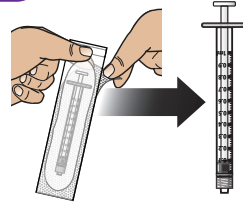


Figure L

- Remove the syringe from its package (Figure L).
Do not let the syringe tip touch your hands or any surface.

2.7

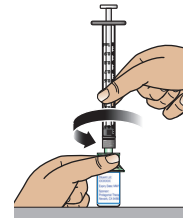


Figure M

- Attach the syringe to the diluent vial adapter by holding the vial on a clean flat surface and screwing the syringe onto the vial adapter by turning clockwise/to the right until you feel resistance (Figure M).

Do not overtighten.

2.8

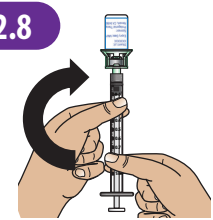


Figure N

- Turn upside down so that the diluent vial is now on top (Figure N).

2.9

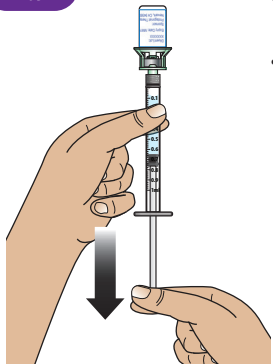


Figure O

- Draw all of the liquid diluent into the syringe by slowly pulling the plunger down.
- Draw as much liquid as you can (Figure O) even if a little bit of air is drawn into the syringe as well.

It is normal for a few drops of liquid to remain in the vial. However, you should draw as much liquid as you can into the syringe.

Be careful, do not pull the plunger out of the syringe.

2.10

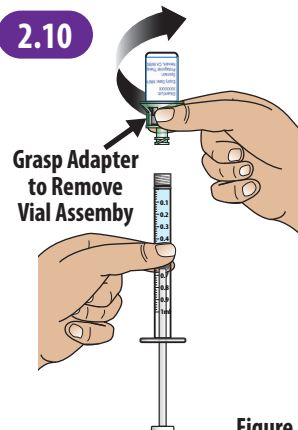


Figure P

- While holding the syringe with one hand, grasp the vial adapter and unscrew the vial assembly (vial and vial adapter) from the filled syringe by turning counter-clockwise/to the left (Figure P).

Do not throw away used vial. Return used vials with attached adapters to the Clinical Site.

2.11

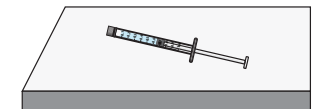


Figure Q

- Set the filled syringe aside on a clean flat surface. Prevent the syringe tip from touching your hands or any surface (Figure Q).

Step 3: Preparing Rusfertide (PTG-300) Syringe

Continue On Next Page

3.1

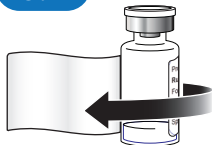


Figure R

- Peel back the label to reveal the side of the PTG-300 drug vial (Figure R).
Do not peel the label all the way off.

3.2

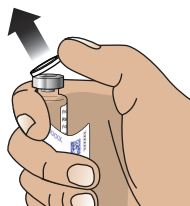


Figure S

- Remove the white cap from the PTG-300 drug vial (Figure S).

3.3



Figure T

- Clean gray rubber stopper on top of PTG-300 drug vial with a new alcohol swab (Figure T). Dispose of used swab.
Do not touch the gray rubber stopper on the top of the vial with your hand after cleaning.

3.4

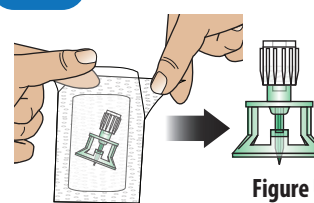


Figure U

- Remove the other vial adapter from its package (Figure U).
Do not touch adapter spike.

3.5

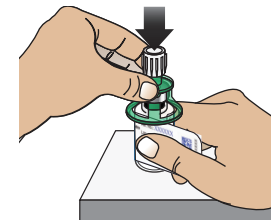


Figure V

- Attach the vial adapter to the drug vial by holding the vial on a clean flat surface and pushing the vial adapter straight down onto the top of vial (Figure V).
Note: The spike on the vial adapter should punch through the gray rubber stopper.

Step 3: Preparing Rusfertide (PTG-300) Syringe (Continued)

3.6



Figure W

- Remove the clear vial adapter cap by holding the vial adapter with one hand, and with the other, unscrew the cap counter-clockwise/to the left until it lifts away (Figure W). Discard the vial adapter cap.

Do not touch the vial adapter tip.

3.7

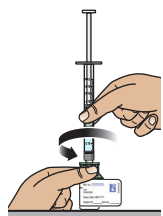


Figure X

- Attach the syringe containing diluent to the PTG-300 vial adapter by holding the vial on a clean flat surface and screwing the syringe onto the vial adapter by turning clockwise/to the right until you feel resistance (Figure X).

Do not overtighten.

3.8

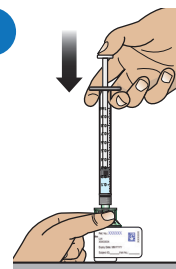


Figure Y

- Inject the diluent into the drug vial by **slowly** pushing down on the syringe plunger until fully depressed (Figure Y).

3.9

**Swirl
Slowly for
60 Seconds**

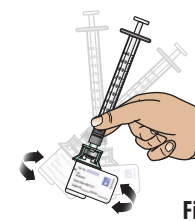


Figure Z

- Mix the diluent and drug by slowly and gently swirling the drug vial **for at least 60 seconds** (Figure Z). The drug may have a foamy appearance.

Do not shake.

Note: Inject drug within 4 hours of mixing it.

3.10

**Let Vial Sit
for
60 Seconds**



Figure AA

- Set the vial on a clean flat surface and **let it sit for at least 60 seconds** to allow the liquid to settle and the foaminess to go away (Figure AA).

3.11

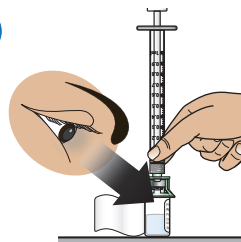


Figure AB

- Once the liquid has settled, inspect the liquid (Figure AB). It should be clear with slight foam, colorless, and free from visible particles.

Do not use the vial if the liquid looks colored or contains particles.

3.12

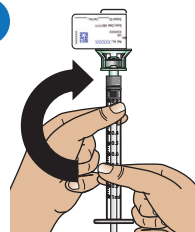


Figure AC

- Turn upside down so that the PTG-300 drug vial is now on top (Figure AC).

3.13

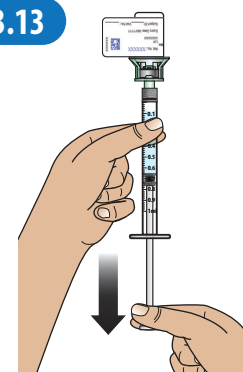


Figure AD

- Draw all of the mixed drug into the syringe by slowly pulling the plunger down (Figure AD). It is normal for a few drops of liquid to remain in the vial.

Be careful, do not pull the plunger out of the syringe.

Note: If a large amount of air is seen, slowly push the air back into the vial so that the syringe is filled with only liquid.

3.14

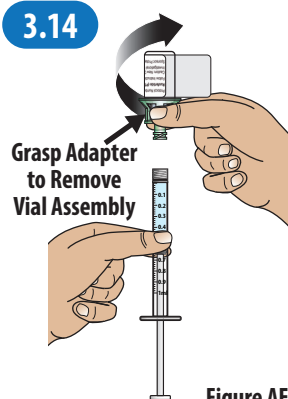


Figure AE

- While holding the syringe with one hand, grasp the vial adapter and unscrew the vial assembly (vial and vial adapter) from the filled syringe by turning counter-clockwise/to the left (Figure AE).

Do not throw away used vial. Return used vials with attached adapters to the Clinical Site.

3.15

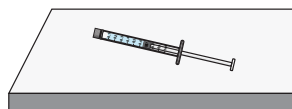


Figure AF

- Set the filled syringe aside on a clean flat surface. Prevent the syringe tip from touching your hands or any surface (Figure AF).

3.16

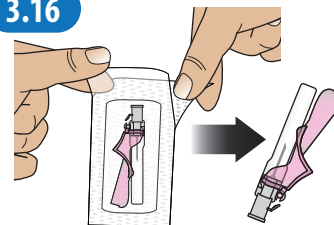


Figure AG

- Remove the needle from packaging (Figure AG). **Do not** touch the bottom/open end of the needle.

3.17



Figure AH

- Holding the syringe in one hand, screw the needle onto the syringe by turning clockwise/to the right until you feel resistance (Figure AH).

3.18

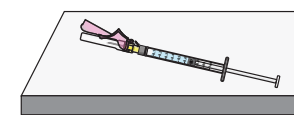


Figure AI

- Set the prepared syringe aside on a clean flat surface (Figure AI).

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Step 4: Preparing The Injection Site

4.1

Front View

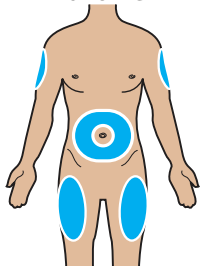


Figure AJ

- Choose one of the following recommended injection sites (Figure AJ):
 - Abdomen** (at least 2 inches away from the navel [belly button])
 - Middle area of the thigh**
 - If you are a caregiver preparing and administering the injection, you may also use the outer area of the patient's upper arm if necessary.

Do not select a site where the skin is tender, bruised, red, irritated, hard or broken.

Do not inject into the same spot twice in a row. Rotate sites between injections. If needed write down or log your injection sites.

4.2



Figure AK

- Clean the chosen injection site with a new alcohol swab (Figure AK). Dispose of used swab.
- Allow to air dry.

Step 5: Injecting Rusfertide (PTG-300)

5.1

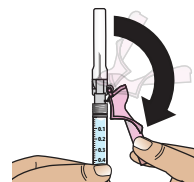


Figure AL

- Pull the pink needle shield back (Figure AL).

5.2

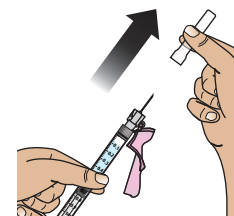


Figure AM

- Remove the needle cap by holding the syringe with one hand and **firmly pulling the cap straight off** with the other (Figure AM).
- Keep your hand moving away from the needle as you pull the cap off so you don't get stuck by the needle.

5.3

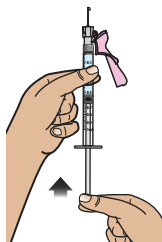


Figure AN

- Remove air from syringe, if needed (Figure AN). To do this:
 - Hold the syringe with the needle tip pointing straight up.
 - Tap the syringe to move any air or bubbles to the syringe tip.
 - Slowly and carefully push the syringe plunger to remove the air or bubbles. Stop pushing when liquid is visible at end of needle.
 - No more than 1 to 2 drops of liquid should be expelled. It is okay if a small air gap/bubble is left in the syringe.

5.4



Figure AO

- Use one hand to pinch the skin at the injection site (Figure AO). This allows you to insert the needle into the fatty tissue just under the skin.

5.5

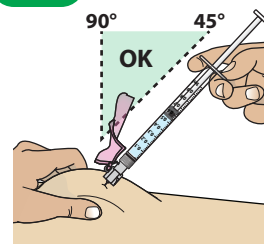


Figure AP

- Insert the needle into the pinched skin at a 45-90 degree angle (Figure AP).
- Then release the pinched skin.

5.6

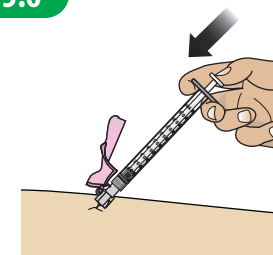


Figure AQ

- Slowly push the plunger to inject all the PTG-300 drug** (Figure AQ).
- Once all liquid is injected, pull the needle and syringe out of the skin at the same angle as you inserted it.

Step 6: Disposing of Rusfertide (PTG-300)

6.1

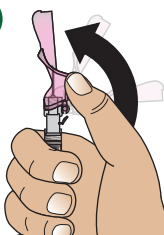


Figure AR

- Carefully push the pink needle shield over the needle until it snaps into place and covers the needle (Figure AR).

6.2

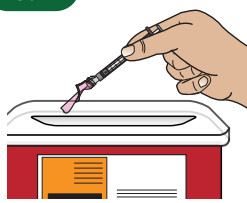


Figure AS

- Immediately place the used syringe into the Sharps Container (Figure AS). **Do not** throw the needle and syringe in your household trash.

The needle and syringe should NOT be reused.

Always keep the Sharps Container out of reach of children.

6.3

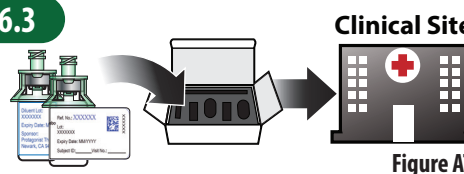


Figure AT

- Return both used vials with attached adapters to the Clinical Site** (Figure AT).
- Throw other materials into household trash.** Used vial caps, used vial adapter caps, used alcohol swabs and opened packaging may be disposed of in household trash.

Additional Information

- For additional information on how to use the PTG-300 contact the Clinical Site.**