

PATIENT INFORMATION
HEPCLUDEX® (hep-CLUE-decks)
(bulevirtide-gmod)
for injection, for subcutaneous use

What is the most important information I should know about HEPCLUDEX?

HEPCLUDEX can cause serious side effects, including:

- **Worsening of hepatitis delta virus (HDV) and hepatitis B virus (HBV) infection. Your HDV or HBV infection may get worse (flare-up) if you stop taking HEPCLUDEX, especially if you have cirrhosis. A "flare-up" is when your HDV or HBV infection suddenly returns in a worse way than before.**
 - Do not run out of HEPCLUDEX. Refill your prescription or talk to your healthcare provider before your HEPCLUDEX is all gone.
 - Do not stop taking HEPCLUDEX without first talking to your healthcare provider.
 - If you stop taking HEPCLUDEX, your healthcare provider will need to check your health often and do blood tests regularly for at least 6 months to check your liver, and may give you medicine to treat your virus infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking HEPCLUDEX.

For more information about side effects, see "What are the possible side effects of HEPCLUDEX?"

What is HEPCLUDEX?

HEPCLUDEX is a prescription medicine used to treat chronic (long-lasting) hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

It is not known if HEPCLUDEX is safe and effective in children less than 18 years of age.

Before taking HEPCLUDEX, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if HEPCLUDEX can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if HEPCLUDEX can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with HEPCLUDEX.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take HEPCLUDEX?

See the **Instructions for Use** for instructions on **how to prepare and** inject your **prescribed** dose of **HEPCLUDEX**.

- Take HEPCLUDEX exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- HEPCLUDEX is given as an injection under your skin (subcutaneous) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare and inject HEPCLUDEX before you use it for the first time.
- Take HEPCLUDEX 1 time each day.
- **Do not** change your dose or stop taking HEPCLUDEX without first talking with your healthcare provider. Stay under a healthcare provider's care when taking HEPCLUDEX.
- **Do not** miss a dose of HEPCLUDEX.
- If you miss a dose, take that dose as soon as possible on that day. However, if it is almost time for your next dose, skip the missed dose and go back to the regular dosing schedule.
- If you take too much HEPCLUDEX, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your HEPCLUDEX supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because your HDV and HBV infection may get worse (flare-up) if you stop taking HEPCLUDEX.

What are the possible side effects of HEPCLUDEX?

HEPCLUDEX can cause serious side effects, including:

- See **"What is the most important information I should know about HEPCLUDEX?"**

- **Allergic reactions, including severe allergic reactions (anaphylaxis).** Stop taking HEPCLUDEX and tell your healthcare provider or get emergency medical help right away if you develop any signs or symptoms of a severe allergic reaction, including:

- trouble swallowing or breathing
- throat tightness
- severe rash, hives, or itching
- swelling of the mouth, lips, tongue, or face
- dizziness or fainting
- stomach area pain, nausea, diarrhea, or vomiting

The most common side effects of HEPCLUDEX include:

- injection site reactions, including infection, redness, itching, swelling, bruising, rash, and pain at the injection site
- headache
- stomach area pain
- feeling tired
- itchy skin

These are not all of the possible side effects of HEPCLUDEX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store HEPCLUDEX?

- Store HEPCLUDEX vials at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- After mixing, use HEPCLUDEX vial right away. Throw away (discard) unused portion.

Keep HEPCLUDEX and all medicines out of reach of children.

General information about the safe and effective use of HEPCLUDEX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HEPCLUDEX for a condition for which it was not prescribed. Do not give HEPCLUDEX to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HEPCLUDEX that is written for health professionals.

What are the ingredients in HEPCLUDEX?

Active ingredient: bulevirtide-gmod

Inactive ingredients: histidine, mannitol, and sucrose, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

Manufactured by: Gilead Sciences, Inc., Foster City, CA 94404

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For more information, call 1-800-445-3235 or go to www.HEPCLUDEX.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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INSTRUCTIONS FOR USE

HEPCLUDEX® [hep-CLUE-decks]

(bulevirtide-gmod) for injection, for subcutaneous use single-dose vial

This Instructions for Use contains information on how to prepare and inject HEPCLUDEX. Read this Instructions for Use before you start using HEPCLUDEX and each time you get a refill. There may be new information.

Do not use HEPCLUDEX unless you have been trained by your healthcare provider. Your healthcare provider should show you or your caregiver how to prepare and inject HEPCLUDEX before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider.

- Read the Patient Information that comes with HEPCLUDEX for more information.
- If you have any problems using HEPCLUDEX, including if you do not give a full dose of medicine, contact your healthcare provider.

Important Information You Need to Know Before Injecting HEPCLUDEX:

- Your carton of HEPCLUDEX contains 30 vials. This is a 30-day supply of medicine.
- HEPCLUDEX comes as a powder or cake in a vial. HEPCLUDEX must be mixed and dissolved with Sterile Water for Injection before use.
- Mixed HEPCLUDEX must be used right away. **Do not** reuse or save mixed HEPCLUDEX for later use.
- Your pharmacy will provide you with the following supplies for mixing and injecting HEPCLUDEX:
 - Transfer Needles
 - Empty Syringes
 - Sterile Water for Injection Vials
 - Injection Needles
- **Note: The supplies not included in the HEPCLUDEX carton may slightly differ in size, shape and color from the figures in this Instructions for Use. These instructions provide the steps to mix and inject HEPCLUDEX using an example set of supplies. If you have any questions, contact your healthcare provider or pharmacist.**
- Only use the Sterile Water for Injection Vial provided by your pharmacy to mix HEPCLUDEX. Sterile Water for Injection is different from bottled water or water from a faucet. **Sterile Water for Injection Vials are for one-time use only and must be thrown away (disposed of) after that use, even if there is water remaining in the vial. Reusing Sterile Water for Injection Vials may lead to infection.**
- **Do not touch the needle or syringe tip or allow the needle or syringe tip to touch any other surface.** If you touch the needle or syringe tip or allow the needle or syringe tip to touch any other surface, throw them away in a sharps disposal container (see “**Disposing of Used Needles**”) and use a new needle or syringe. Touching the needle or syringe tip would make it non-sterile and could lead to an infection.
- **Do not reuse any of the supplies.** Throw away any used Transfer Needles and Injection Needles in a sharps disposal container. See “**Disposing of Used Needles**”.

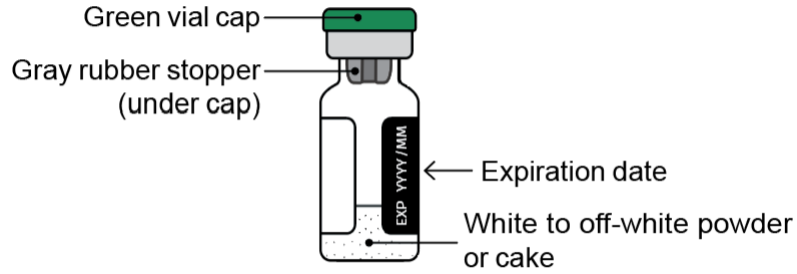
How should I store HEPCLUDEX?

- Store HEPCLUDEX Vials at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- After mixing, use the HEPCLUDEX Vial right away. Throw away (discard) unused portion.
- Store all other supplies according to the manufacturer instructions.
- **Keep HEPCLUDEX Vials, all supplies, and all medicines out of the reach of children.**

Guide to Parts

HEPCLUDEX Vial

HEPCLUDEX Vial

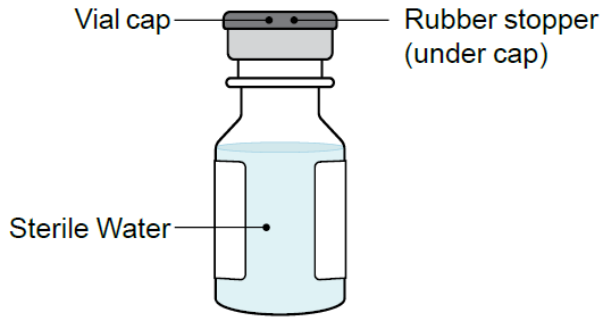


Supplies Needed to Mix HEPCLUDEX

(not included in the HEPCLUDEX carton; supplies from the pharmacy may look different than supplies pictured here)

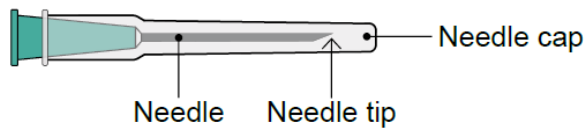
Sterile Water for Injection Vial

(used to mix HEPCLUDEX)

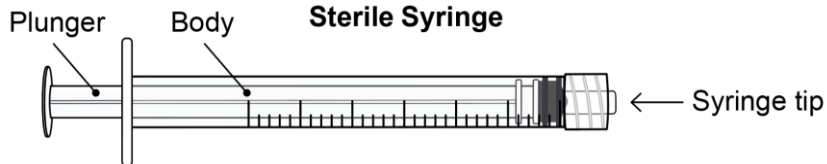


Sterile Transfer Needles

(used to transfer Sterile Water for Injection to HEPCLUDEX Vial and to withdraw mixed HEPCLUDEX)



Sterile Syringe



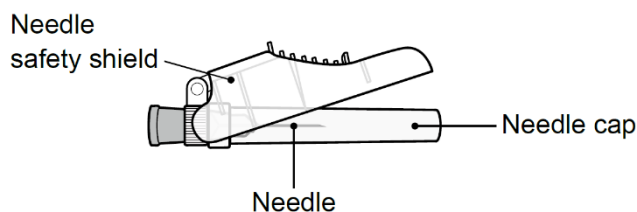
Supplies Needed to Inject HEPCLUDEX After Mixing

(not included in the HEPCLUDEX carton; supplies from the pharmacy may look different than supplies pictured here)

Sterile Injection Needle with Safety Shield

(used to inject **after** HEPCLUDEX has been mixed)

Do not insert the Injection Needle into the vials



Note: When the needle safety shield is closed over the Injection Needle, the needle is locked and cannot be used.

Additional Supplies Needed (may be provided by pharmacy)



Sharps disposal container



Adhesive bandage



Cotton ball or gauze

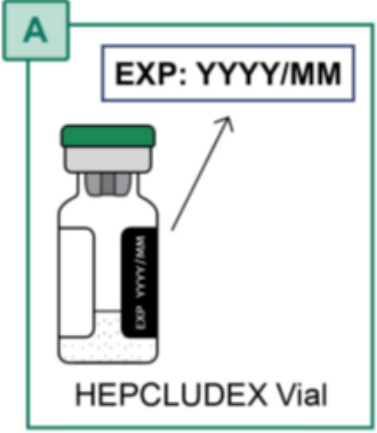
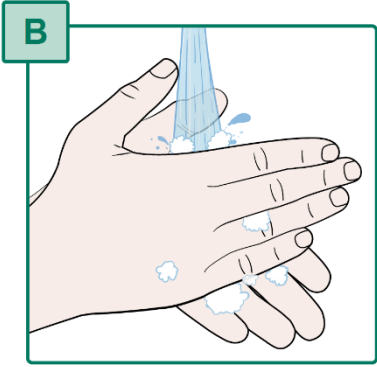
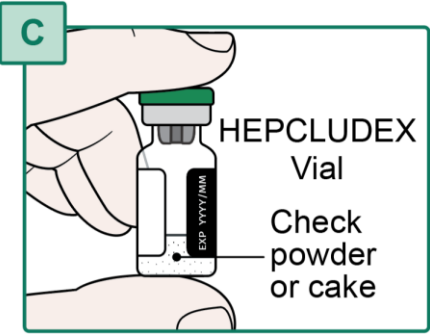


Alcohol swabs

Gather HEPCLUDEX Vial and Supplies

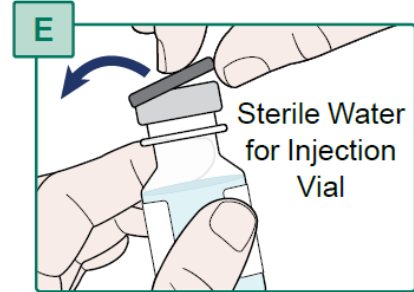
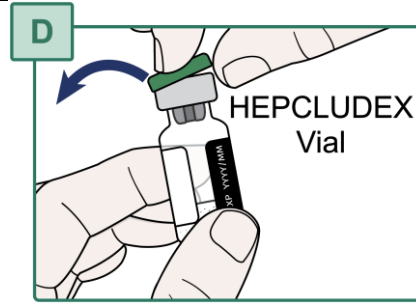
Step 1.

- Take 1 vial from the HEPCLUDEX Vial carton.
- Gather the supplies for mixing and injecting (supplies provided by pharmacy):
 - 2 Sterile Transfer Needles (21G, 1 inch)
 - 1 Sterile Water for Injection Vial (5 mL or 10 mL)
 - 1 Sterile Syringe (3 mL)
 - 1 Sterile Injection Needle with safety shield (27G, ½ inch)
- Gather additional supplies needed (may be provided by pharmacy):
 - 1 sharps disposal container
 - 1 adhesive bandage
 - 1 cotton ball or gauze
 - 3 alcohol swabs
- Place the HEPCLUDEX Vial and all supplies on a clean flat surface.

<p>Step 2.</p> <ul style="list-style-type: none"> • Check the expiration dates (YYYY/MM) on the HEPCLUDEX Vial (see Figure A) and on the supplies for mixing and injecting HEPCLUDEX. • Do not use if any of the expiration dates have passed. • Check the HEPCLUDEX Vial and the supplies packaging for damage. • Do not use if the vial or supplies packaging has been dropped or appears damaged. 	 <p>Figure A shows a vial of HEPCLUDEX. A label on the vial reads 'EXP: YYYY/MM'. An arrow points from the label to the text 'EXP: YYYY/MM' above the vial. The vial is labeled 'HEPCLUDEX Vial' at the bottom.</p>
<p>Step 3.</p> <ul style="list-style-type: none"> • Wash your hands well with soap and water (see Figure B). 	 <p>Figure B shows a pair of hands being washed under a stream of water. Soap suds are visible on the hands.</p>
<p>Prepare HEPCLUDEX Vial, Sterile Water for Injection Vial, and Syringe</p>	
<p>Step 4.</p> <ul style="list-style-type: none"> • Check the HEPCLUDEX Vial, Sterile Water for Injection Vial, Transfer Needles, Syringe, and Injection Needle (supplies) for damage. • Check the powder or cake in the HEPCLUDEX Vial. The powder or cake should be a white to off-white color (see Figure C). • Do not use if: <ul style="list-style-type: none"> ○ the vials or supplies look damaged or have dropped onto a hard surface. ○ the vial caps are missing, loose, or damaged. ○ the powder or cake in the HEPCLUDEX Vial is discolored. 	 <p>Figure C shows a hand holding a vial of HEPCLUDEX. The vial is labeled 'HEPCLUDEX Vial' and 'Check powder or cake'. The vial is labeled 'EXP: YYYY/MM'.</p>

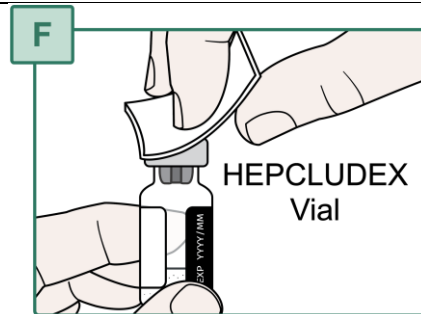
Step 5.

- Remove the cap from the HEPCLUDEX Vial (see **Figure D**).
- Remove the cap from the Sterile Water for Injection Vial (see **Figure E**).



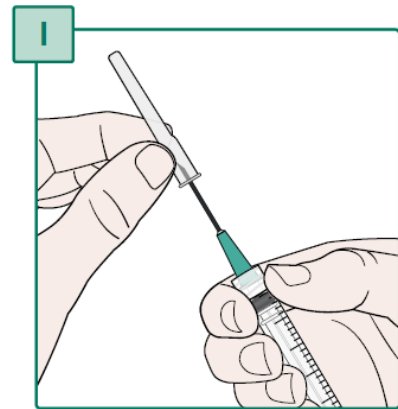
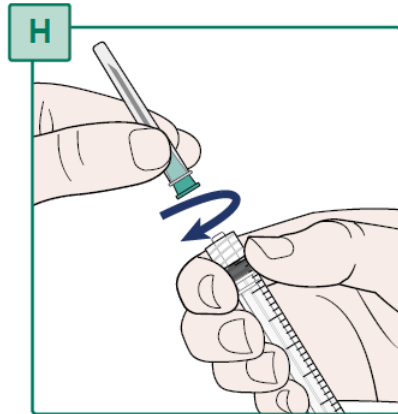
Step 6.

- Clean the rubber stopper of the HEPCLUDEX Vial with an alcohol swab (see **Figure F**).
- With a different alcohol swab, clean the rubber stopper of the Sterile Water for Injection Vial (see **Figure G**).
- **Do not** touch the rubber stoppers after they have been cleaned.



Step 7.

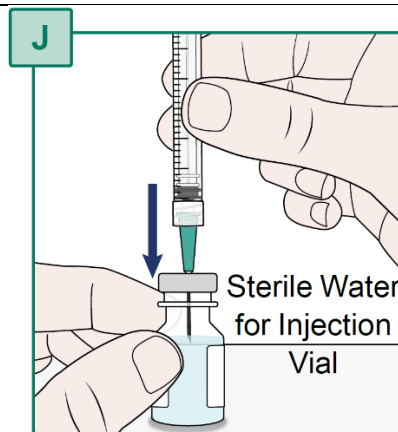
- Remove a Transfer Needle and Syringe from their packaging.
- Hold the Syringe and the Transfer Needle firmly.
- Turn the Transfer Needle to the right (clockwise) onto the Syringe until it is fully connected (see **Figure H**).
- Remove the needle cap from the Transfer Needle by pulling it straight off (see **Figure I**). **Keep the needle cap for later use.**
- **Do not** use the Transfer Needle if it is bent or appears damaged.



Mix HEPCLUDEX

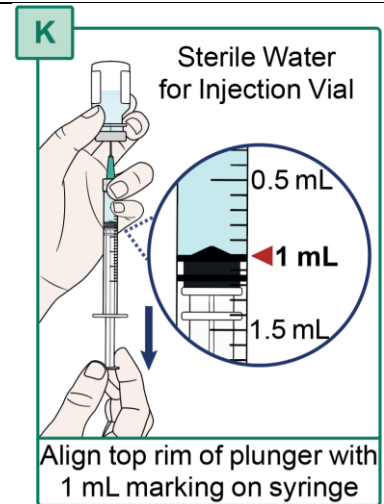
Step 8.

- Hold the Sterile Water for Injection Vial on a flat surface.
- Insert the Transfer Needle all the way into the Sterile Water for Injection Vial by pushing it straight through the center of the rubber stopper (see **Figure J**).



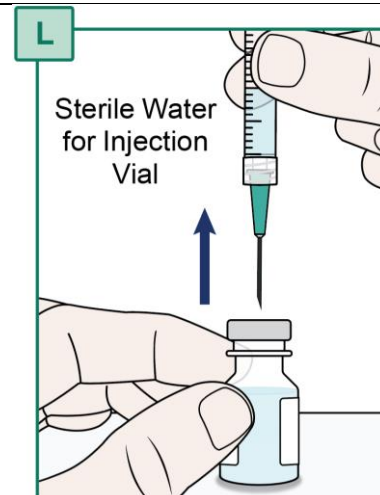
Step 9.

- Turn the Sterile Water for Injection Vial and Syringe upside down so the vial is pointing upwards.
- Be sure that the tip of the Transfer Needle is in the liquid.
- With one hand, keep the Syringe and Transfer Needle in place.
- With the other hand, carefully **pull the plunger down until the top rim of the plunger lines up with the 1 mL marking on the Syringe** (see **Figure K**).
- If you see large air gaps in the Syringe, push the plunger all the way up and repeat **Step 9**.



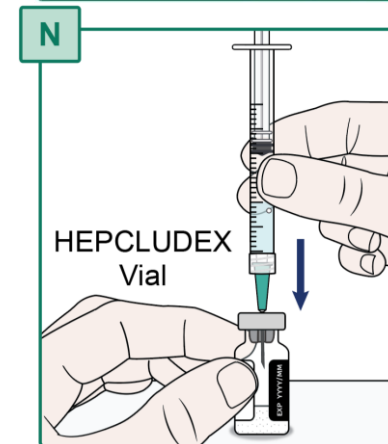
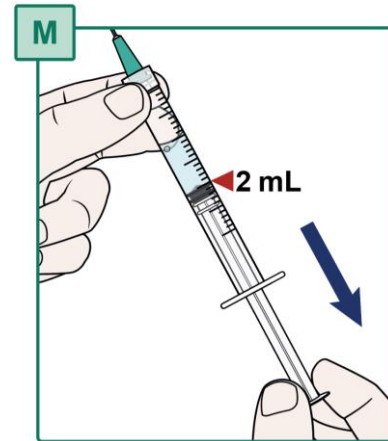
Step 10.

- Hold the plunger in place and turn the Sterile Water for Injection Vial and Syringe upright. Hold the vial on a flat surface.
- Remove the water-filled Syringe with the Transfer Needle attached from the Sterile Water for Injection Vial by holding the Syringe body and pulling it straight up (see **Figure L**).
- **Do not** touch the Transfer Needle or let it touch any surface. See “**Important Information You Need to Know Before Injecting HEPCLUDEX**”.
- **Throw away the Sterile Water for Injection Vial into the household trash. Sterile Water for Injection Vials are for one-time use only** and must be thrown away (disposed of) after that use, even if there is water remaining in the vial. Reusing Sterile Water for Injection Vials may lead to infection.



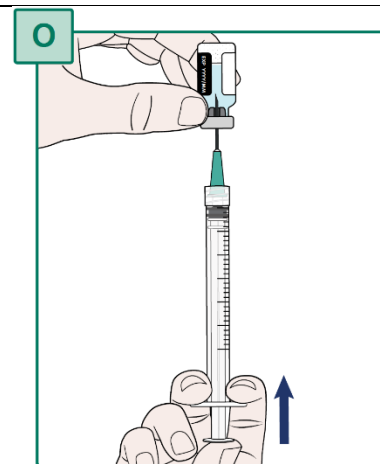
Step 11.

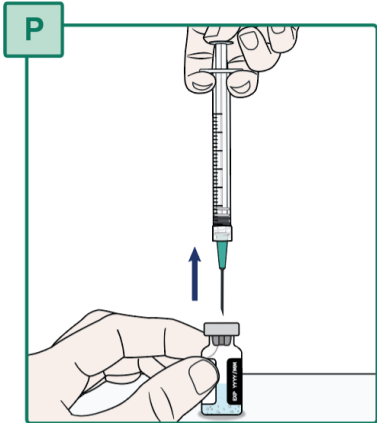
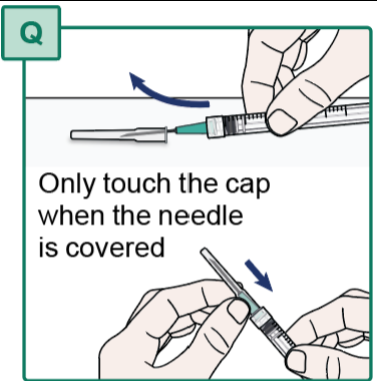
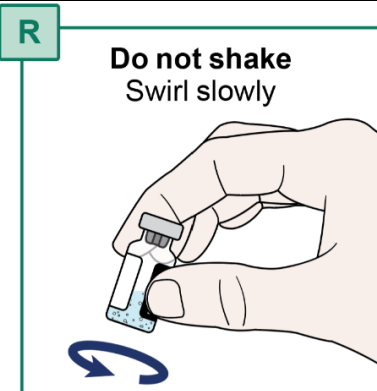
- Pull the plunger all the way down to the 2 mL marking of the Syringe to add air to the Syringe (see **Figure M**).
- **Do not** pull the plunger out of the Syringe.
- Get the HEPCLUDEX Vial and hold the vial on a flat surface.
- Insert the Transfer Needle all the way into the HEPCLUDEX Vial by pushing it straight through the center of the rubber stopper (see **Figure N**).

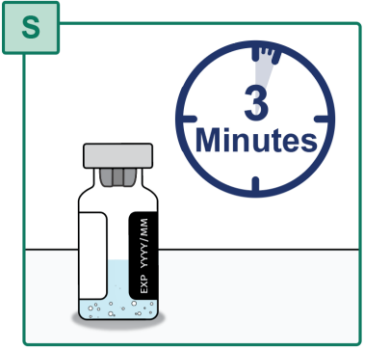
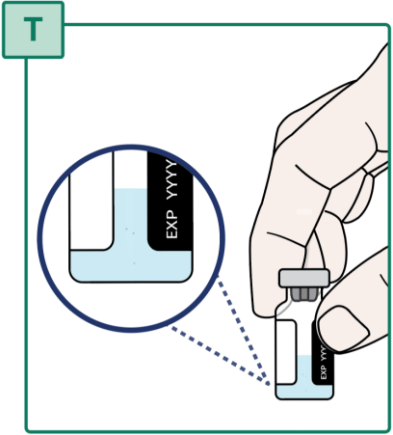
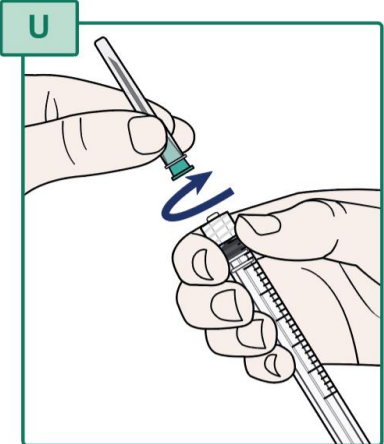


Step 12.

- Turn the HEPCLUDEX Vial and Syringe upside down so the vial is pointing upwards.
- **Slowly** push the plunger all the way up until the Syringe is empty (see **Figure O**).
- Pushing the plunger all the way up fills the HEPCLUDEX Vial with air and the Sterile Water for Injection.

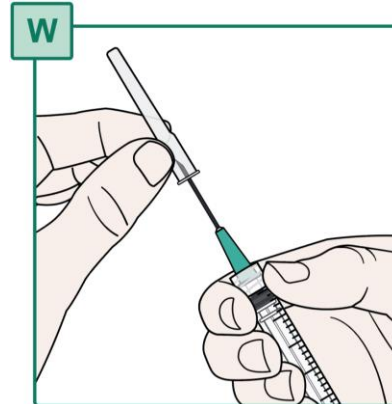
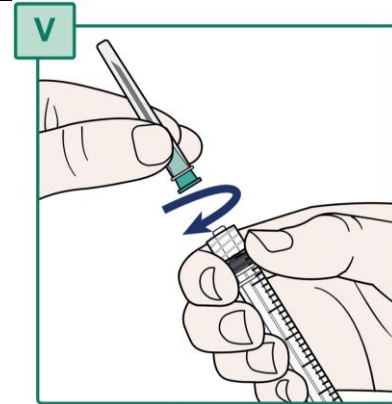


<p>Step 13.</p> <ul style="list-style-type: none"> • Hold the plunger in place and turn the HEPCLUDEX Vial and Syringe upright. • Hold the vial on a flat surface. • Remove the empty Syringe with the Transfer Needle attached from the HEPCLUDEX Vial by pulling it straight up (see Figure P). 	 <p>P</p>
<p>Step 14.</p> <ul style="list-style-type: none"> • Using one hand, slide the Transfer Needle into its cap and scoop upwards to cover the needle (see Figure Q). • When the Transfer Needle is covered, carefully push the needle cap towards the Syringe to fully attach it. • Do not touch the Transfer Needle. See “Important Information You Need to Know Before Injecting HEPCLUDEX”. • Keep the Syringe with Transfer Needle attached for later use in Step 18. 	 <p>Q</p> <p>Only touch the cap when the needle is covered</p>
<p>Step 15.</p> <ul style="list-style-type: none"> • Slowly swirl the HEPCLUDEX Vial for a few seconds to mix the powder with the Sterile Water for Injection (see Figure R). • If there is powder stuck to the vial wall or rubber stopper, continue to swirl the vial slowly until it is removed. • Do not shake the vial. 	 <p>R</p> <p>Do not shake Swirl slowly</p>

<p>Step 16.</p> <ul style="list-style-type: none"> Place the HEPCLUDEX Vial upright on a flat surface. Wait for the powder to fully dissolve (see Figure S). This may take up to 3 minutes. 	 <p>Figure S shows a vial of HEPCLUDEX medicine on a flat surface. To the right of the vial is a circular clock face with the number '3' and the word 'Minutes' inside, indicating a 3-minute wait time for the powder to dissolve.</p>
<p>Step 17.</p> <ul style="list-style-type: none"> Check that the powder is fully dissolved. The medicine should look clear without any clumps or particles (see Figure T). It is normal to see foam in the medicine. Do not use the medicine if you see particles or clumps that have not completely dissolved, including powder stuck to the vial wall or rubber stopper. Repeat Steps 15 and 16 if the powder is not fully dissolved. 	 <p>Figure T shows a hand holding a vial of HEPCLUDEX medicine. A magnifying glass is positioned over the vial, showing a close-up of the liquid inside, which is clear and free of clumps or particles.</p>
<p>Step 18.</p> <ul style="list-style-type: none"> Hold the Syringe firmly (see Figure U). Turn the capped Transfer Needle to the left (counterclockwise) to remove it from the Syringe. Throw away (dispose of) the Transfer Needle in the sharps disposal container. See “Disposing of Used Needles”. Do not touch the Syringe tip or allow it to touch any surface. See “Important Information You Need to Know Before Injecting HEPCLUDEX”. 	 <p>Figure U shows a hand holding a syringe. Another hand is shown turning a capped transfer needle to the left (counterclockwise) to remove it from the syringe. A blue curved arrow indicates the direction of rotation.</p>

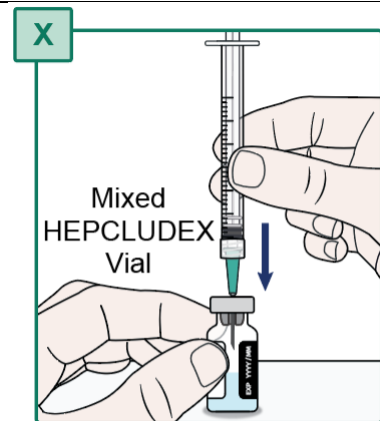
Step 19.

- Remove the second Transfer Needle from its packaging.
- Hold the Syringe and the Transfer Needle firmly.
- Turn the Transfer Needle to the right (clockwise) onto the Syringe until it is fully connected (see **Figure V**).
- Remove the needle cap from the Transfer Needle by pulling it straight off (see **Figure W**). **Keep the needle cap for later use.**
- **Do not** use the Transfer Needle if it is bent or appears damaged.



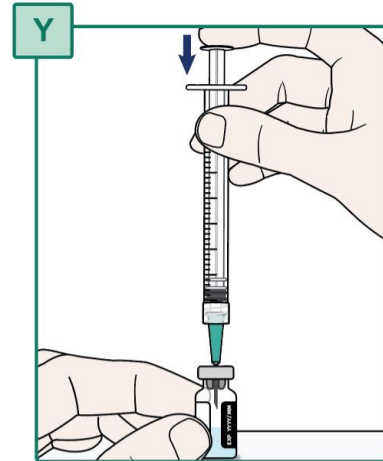
Step 20.

- Hold the mixed HEPCLUDEX Vial on a flat surface.
- Insert the Transfer Needle all the way into the HEPCLUDEX Vial by pushing it straight through the center of the rubber stopper (see **Figure X**).



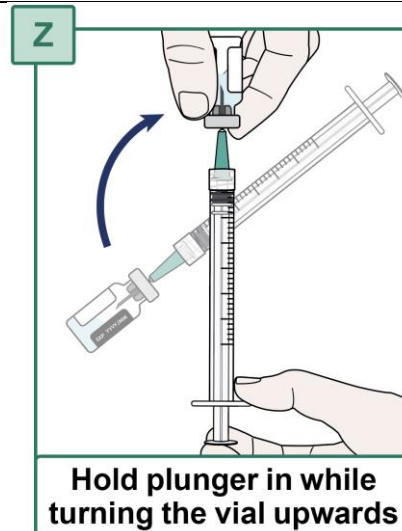
Step 21.

- Check the plunger is pushed all the way down. If the plunger has risen, push the plunger all the way down (see **Figure Y**). All air should be pushed out of the Syringe.
- Keep the plunger fully pushed down.



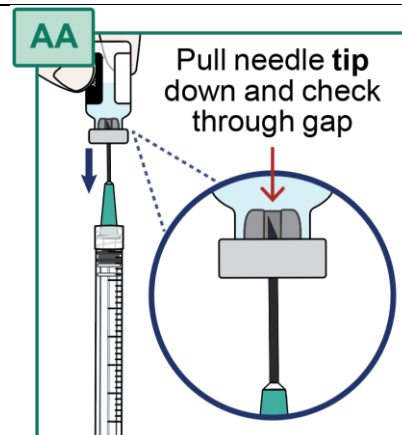
Step 22.

- While pushing down on the plunger, turn the HEPCLUDEX Vial and Syringe so that the vial is pointing upwards (see **Figure Z**).
- **Do not** let go of the plunger.
- If you let go of the plunger before the vial is pointing upwards, turn the vial so it is facing downwards again and repeat **Step 21**.



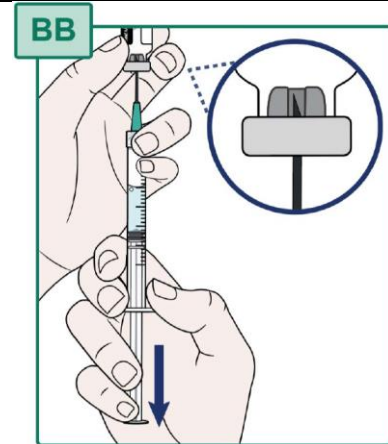
Step 23.

- Hold the HEPCLUDEX Vial pointing upwards.
- Pull the Transfer Needle down until the needle **tip** is near the bottom of the rubber stopper in the vial. Check the position through the gap in the rubber stopper (see **Figure AA**).
- **Do not** completely remove the needle from the vial.



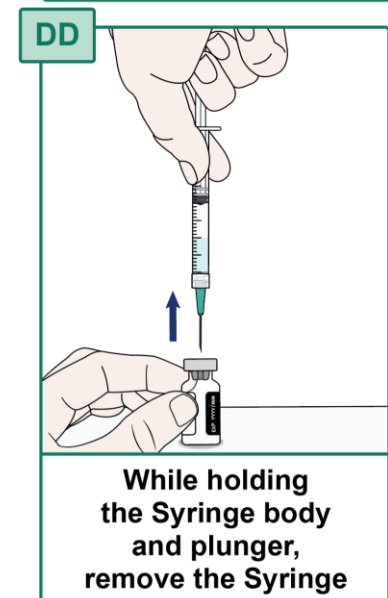
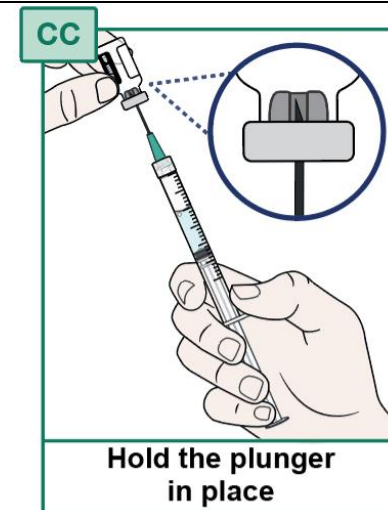
Step 24.

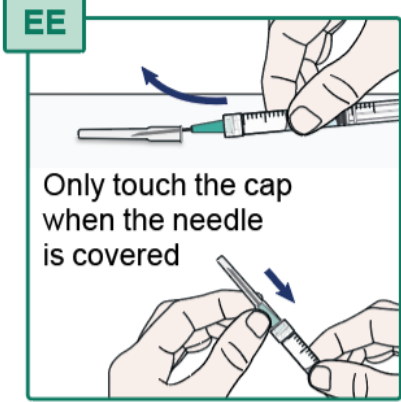
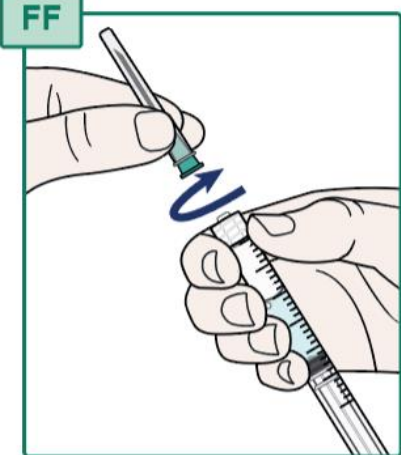
- Keep the Transfer Needle tip in place inside the HEPCLUDEX Vial (see **Figure BB**).
- Carefully pull the plunger until **all the medicine** is removed from the HEPCLUDEX Vial (see **Figure BB**).
- Hold the plunger in place to keep all the medicine in the Syringe.
- An air gap above the medicine is normal at this step and will be removed before injection. Small air bubbles in the medicine are normal.
- Leftover foam in the vial is normal.
- **Do not** pull the plunger out of the Syringe.



Step 25.

- Before continuing, check that all the liquid medicine is removed from the HEPCLUDEX Vial (see **Figure CC**).
- Hold the plunger in place and turn the HEPCLUDEX Vial and Syringe upright.
- Hold the vial on a flat surface.
- While holding the Syringe body and plunger in place, remove the Syringe with the Transfer Needle attached from the HEPCLUDEX Vial (see **Figure DD**).
- **Do not** push the plunger until ready to inject. Pushing the plunger will cause medicine to come out of the Syringe.
- Throw away the HEPCLUDEX Vial into the household trash.

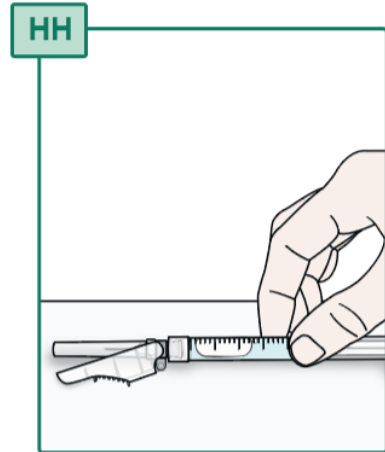
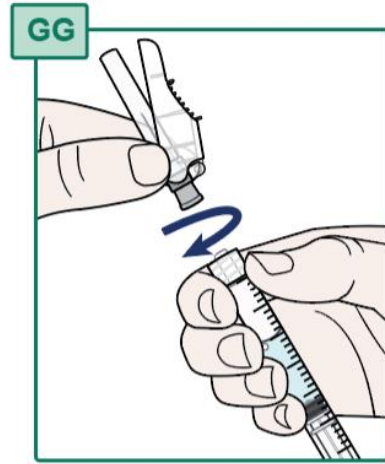


<p>Step 26.</p> <ul style="list-style-type: none"> Using one hand, slide the Transfer Needle into its cap and scoop upwards to cover the needle (see Figure EE). When the Transfer Needle is covered, carefully push the needle cap towards the Syringe to fully attach it. Do not touch the Transfer Needle. See “Important Information You Need to Know Before Injecting HEPCLUDEX”. 	 <p>EE</p> <p>Only touch the cap when the needle is covered</p>
<p>Step 27.</p> <ul style="list-style-type: none"> Hold the Syringe firmly (see Figure FF). Turn the capped Transfer Needle to the left (counterclockwise) to remove it from the Syringe. Throw away (dispose of) the Transfer Needle in the sharps disposal container. See “Disposing of Used Needles”. Do not touch the Syringe tip or allow it to touch any surface. See “Important Information You Need to Know Before Injecting HEPCLUDEX”. 	 <p>FF</p>

Inject HEPCLUDEX

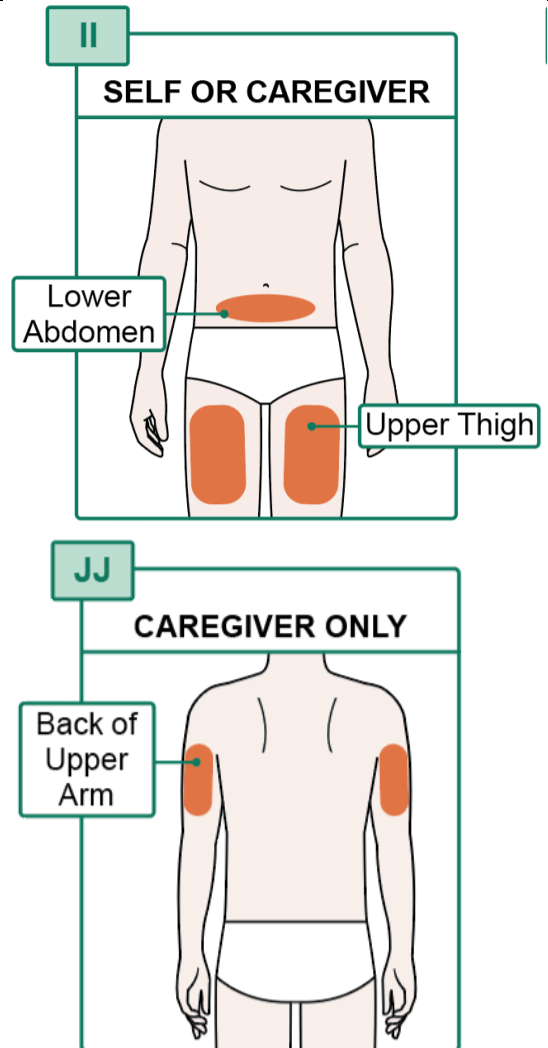
Step 28.

- Remove the Injection Needle from the packaging.
- Hold the Syringe firmly (see **Figure GG**).
- Turn the Injection Needle to the right (clockwise) onto the Syringe until it is fully connected (see **Figure GG**).
- Place the Syringe with the Injection Needle attached on a flat surface (see **Figure HH**).
- **Do not** remove the needle cap until you are ready to inject the medicine.
- **Do not** push the Syringe plunger until you are ready to inject the medicine, this may cause liquid to come out.



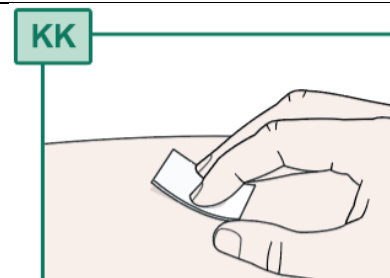
Step 29.

- To inject yourself, choose a site on your lower abdomen (stomach) or upper thighs (see **Figure II**).
- If someone else is injecting the medicine for you, they can also choose the back of the upper arms (see **Figure JJ**).
- **Do not** inject into the same site on consecutive days.
- **Do not** inject into moles, scars, bruises, or tattoos or into areas where the skin is red, hard, tender, or injured.
- **Do not** inject into the 1-inch (2.5-cm) area around the belly button (navel).



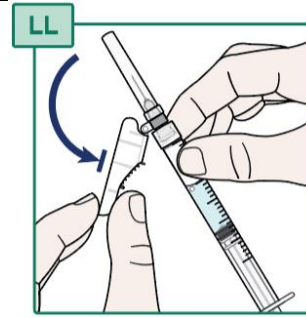
Step 30.

- Clean the injection site with a new alcohol swab (see **Figure KK**).
- Allow the skin to air dry.
- **Do not** touch or blow on the injection site after it has been cleaned.



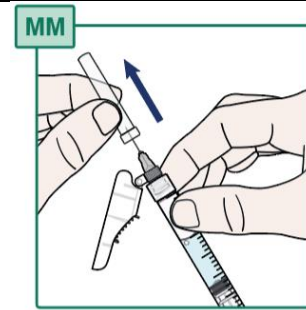
Step 31.

- Hold the Syringe firmly.
- Gently pull back the Injection Needle safety shield (see **Figure LL**).
- **Do not** remove the needle safety shield from the Injection Needle.



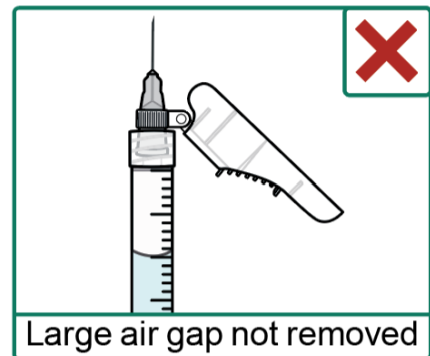
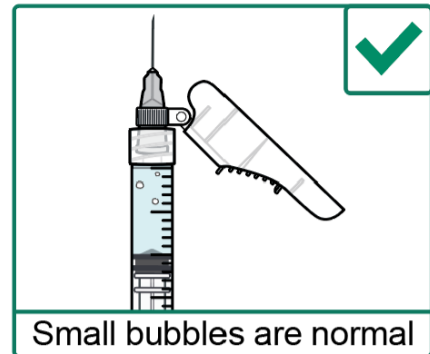
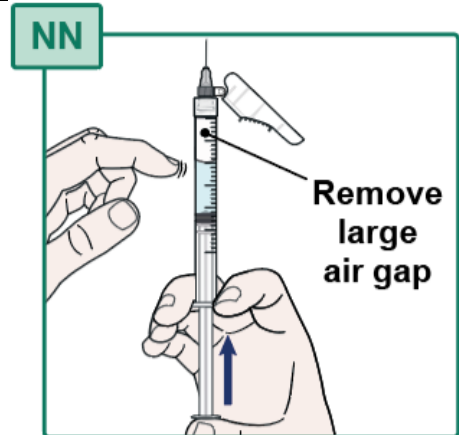
Step 32.

- Carefully pull off the Injection Needle cap (see **Figure MM**) and throw it away into the household trash.
- **Do not** touch the Injection Needle or allow it to touch any other surface. See "**Important Information You Need to Know Before Injecting HEPCLUDEX**".
- **Do not** recap the needle.



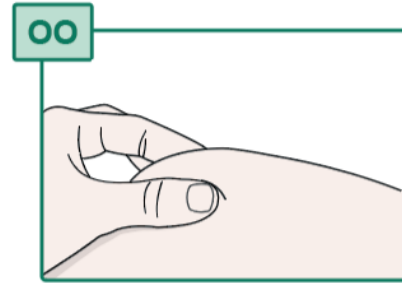
Step 33.

- Make sure the Injection Needle is pointing up and the air gap in the Syringe is at the top.
- If there are large air bubbles, tap the Syringe with your finger until the air bubbles move to the top.
- If there is a large air gap, carefully push the plunger up to remove most of the air gap at the top (see **Figure NN**).
- Small air bubbles are normal and do not need to be removed.
- It is okay for a few drops of medicine to come out of the Syringe.
- **Do not** touch the Injection Needle or allow it to touch any other surface. See “**Important Information You Need to Know Before Injecting HEPCLUDEX**”.



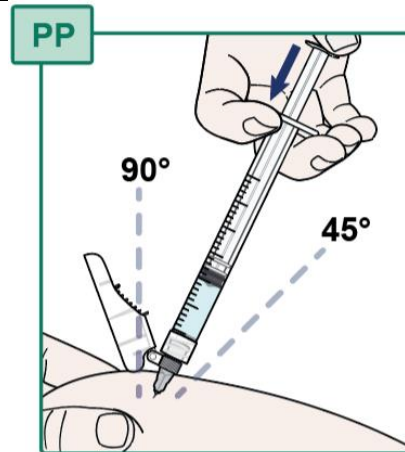
Step 34.

- Pinch the cleaned injection site (see **Figure OO**).



Step 35.

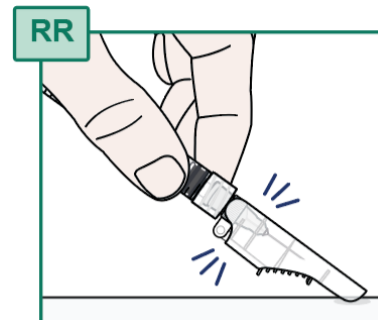
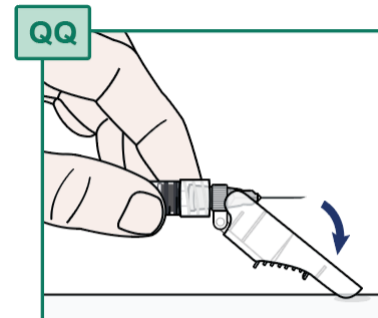
- With your other hand, insert the Injection Needle all the way into the pinched skin at a **45 to 90 degree angle** (see **Figure PP**).
- Slowly push down on the plunger until all of the medicine is injected into the skin.
- Carefully pull out the needle at the same angle as you inserted it.

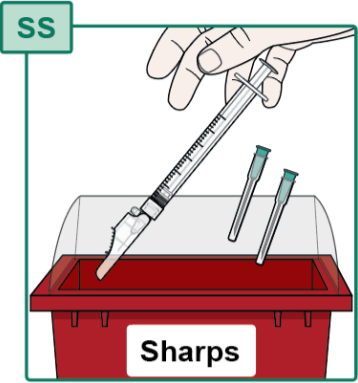
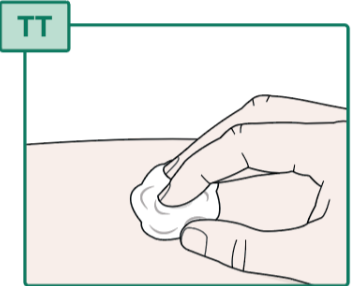


After Injecting HEPCLUDEX

Step 36.

- Right after the injection, place the Injection Needle safety shield on the work surface (see **Figure QQ**).
- Press the needle toward the needle safety shield to cover the needle and lock the safety shield (see **Figure RR**).
- **Do not** touch the Injection Needle. See “**Important Information You Need to Know Before Injecting HEPCLUDEX**”.
- **Do not** remove the needle from the syringe.



<p>Step 37.</p> <ul style="list-style-type: none"> • Throw away (dispose of) the used Syringe with Injection Needle attached in the sharps disposal container (see Figure SS). See “Disposing of Used Needles” below. • Dispose of any remaining waste in the household trash. 	
<p>Step 38.</p> <ul style="list-style-type: none"> • If there is bleeding at the injection site, gently press a cotton ball or gauze over the injection site for several seconds (see Figure TT). • Cover the injection site with an adhesive bandage if needed. • Do not rub the injection site. 	
<p>Disposing of Used Needles</p> <ul style="list-style-type: none"> • Throw away (dispose of) the used Syringe with Injection Needle attached and the used Transfer Needles in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles with your household trash. • If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: <ul style="list-style-type: none"> ○ made of heavy-duty plastic; ○ able to 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 filled, used sharps disposal container. • Keep the sharps disposal container out of the reach of children. 	

For more information, call 1-800-445-3235 or go to www.HEPCLUDEX.com.

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