



INSTRUCTIONS FOR USE

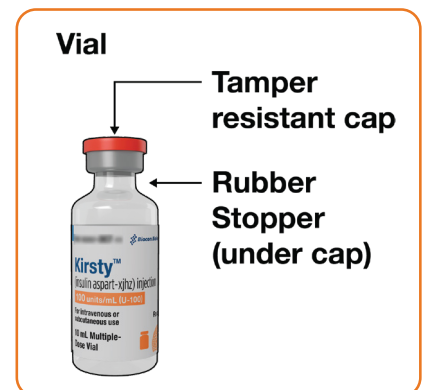
**Kirsty™ [kir-stee] (insulin aspart-xjhz)
injection, for subcutaneous use**

10 mL multiple-dose vial: 100 units/mL (U-100)

Read this Instructions for Use before you start taking KIRSTY and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Supplies you will need to give your KIRSTY injection:

- ▶ 10 mL KIRSTY vial
- ▶ insulin syringe and needle
- ▶ alcohol swabs



Preparing your KIRSTY dose:

- ▶ Wash your hands with soap and water.
- ▶ Before you start to prepare your injection, check the KIRSTY label to make sure that you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- ▶ KIRSTY should look clear and colorless. **Do not** use KIRSTY if it is thick, cloudy, or is colored.
- ▶ **Do not** use KIRSTY past the expiration date printed on the label.

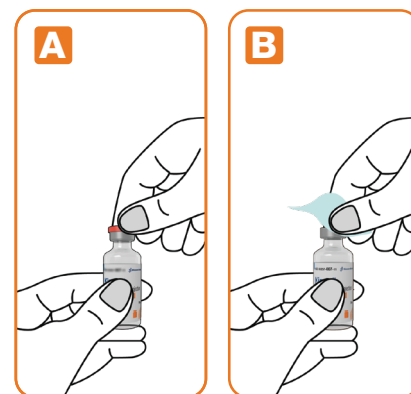


Step 1

Pull off the tamper resistant cap (See Figure A).

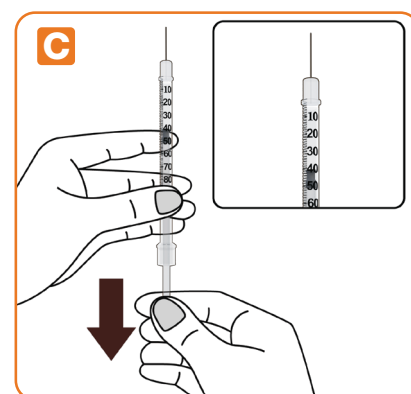
Step 2

Wipe the rubber stopper with an alcohol swab (See Figure B).



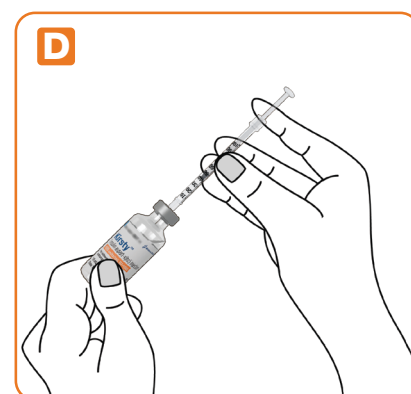
Step 3

Hold the syringe with the needle pointing up.
Pull down on the plunger until the black tip reaches the line for the number of units for your prescribed dose (See Figure C).



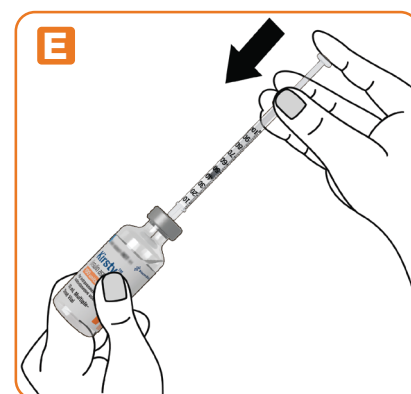
Step 4

Push the needle through the rubber stopper of the KIRSTY vial (See Figure D).



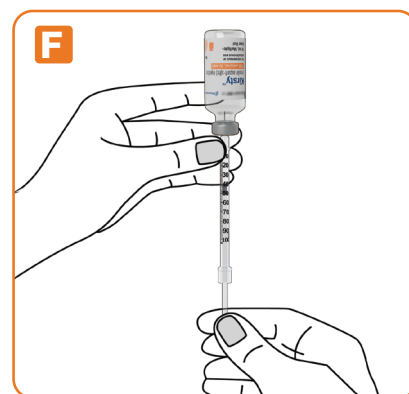
Step 5

Push the plunger all the way in. This puts air into the KIRSTY vial (See Figure E).

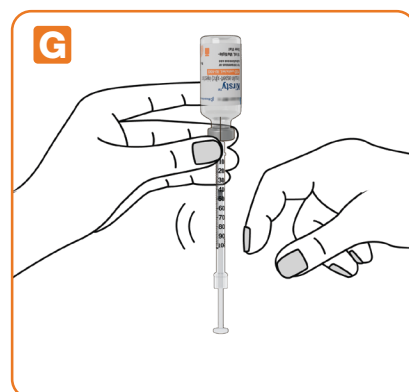


Step 6:

Turn the KIRSTY vial and syringe upside down and slowly pull the plunger down until the black tip is a few units past the line for your dose (See Figure F).

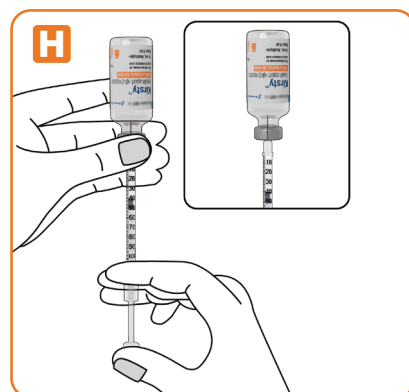


If there are air bubbles, tap the syringe gently a few times to let any air bubbles rise to the top (See Figure G).



Step 7

Slowly push the plunger up until the black tip reaches the line for your KIRSTY dose (See Figure H).

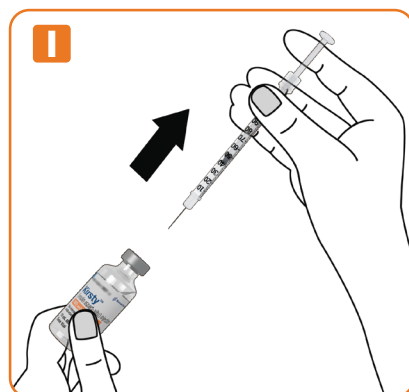


Step 8

Check the syringe to make sure you have the right dose of KIRSTY.

Step 9

Pull the syringe out of the vial's rubber stopper (See Figure I).

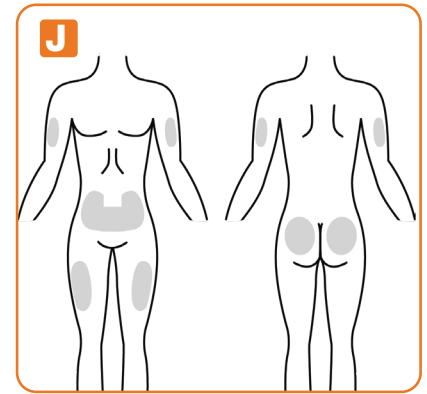


Giving your injection:

- ▶ Inject your KIRSTY exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you need to pinch the skin before injecting.
- ▶ KIRSTY can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms, infused in an insulin pump (continuous subcutaneous infusion into an area of your body recommended in the instructions that come with your insulin pump), or given through a needle in your arm (intravenously) by your healthcare provider.
- ▶ If you inject KIRSTY, change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites. **Do not** use the same injection site for each injection. **Do not** inject where the skin has pits, is thickened, or has lumps. **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- ▶ If you use KIRSTY in an insulin pump, you should change your infusion set and insertion site according to the manufacturer's user manual. KIRSTY can be used with the continuous subcutaneous insulin infusion pumps labeled for use with KIRSTY or NOVOLOG. Read the insulin pump user manual to see if KIRSTY or NOVOLOG can be used. KIRSTY should be given into an area of your body recommended in the instructions that come with your insulin pump. Change (rotate) your insertion sites within the area you choose for each insertion to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the insertion sites. Do not insert into the exact same spot for each insertion. Do not insert where the skin has pits, is thickened, or has lumps. Do not insert where the skin is tender, bruised, scaly or hard, or into scars or damaged skin. The insulin in the reservoir should be changed at least every 7 days or according to the pump user manual, whichever is shorter, even if you have not used all of the insulin.
- ▶ If you use KIRSTY in an insulin pump, see your insulin pump manual for instructions or talk to your healthcare provider.
- ▶ NPH insulin is the only type of insulin that can be mixed with KIRSTY. **Do not** mix KIRSTY with any other type of insulin.
- ▶ KIRSTY should **only** be mixed with NPH insulin if it is going to be injected right away under your skin (subcutaneously).
- ▶ KIRSTY should be drawn up into the syringe **before** you draw up your NPH insulin.
- ▶ Talk to your healthcare provider if you are not sure about the right way to mix KIRSTY and NPH insulin.

Step 10

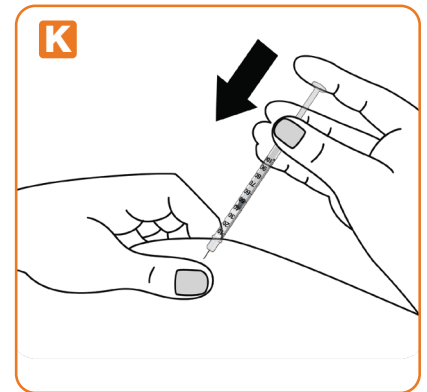
Choose your injection site (stomach area, buttocks, upper legs or upper arms) and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure J).



Step 11

Insert the needle into your skin. Push down on the plunger to inject your dose (See Figure K).

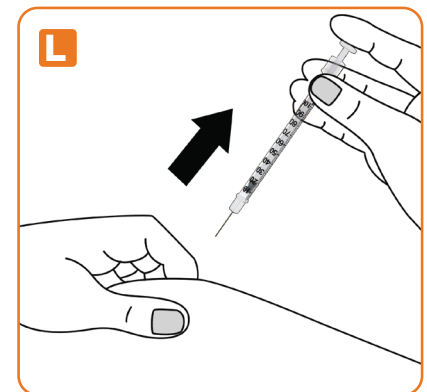
The needle should remain in the skin for at least 6 seconds to make sure you have injected all the insulin.



Step 12

Pull the needle out of your skin. After that, you may see a drop of KIRSTY at the needle tip. This is normal and does not affect the dose you just received (See Figure L).

If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.



After your injection:

- ▶ **Do not** recap the needle. Recapping the needle can lead to a needle stick injury.
- ▶ Put the empty insulin vials, used needles and syringes in a 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 a 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.

How should I store KIRSTY?

- ▶ **Do not** freeze KIRSTY. **Do not** use KIRSTY if it has been frozen.
- ▶ Keep KIRSTY away from heat or light.
- ▶ **All unopened vials:**
 - Store unopened KIRSTY vials in the refrigerator at 36°F to 46°F (2°C to 8°C).
 - Unopened vials may be used until the expiration date printed on the label, if they have been stored in the refrigerator.
 - Unopened vials should be thrown away after 28 days, if they are stored at room temperature up to 86°F (30°C).
- ▶ **After vials have been opened:**
 - Opened KIRSTY vials can be stored in the refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature up to 86°F (30°C).
 - Throw away all opened KIRSTY vials after 28 days, even if they still have insulin left in them.
 - If using KIRSTY in a pump, throw away all opened KIRSTY vials after 19 days.

General information about the safe and effective use of KIRSTY

- ▶ Always use a new syringe and needle for each injection.
- ▶ Do not share syringes or needles.
- ▶ Keep KIRSTY vials, syringes, and needles out of the reach of children.

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

Customer Service

**For Questions or Assistance,
Call Biocon Biologics at 1-833-986-1468**

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