

INSTRUCTIONS for USE
BIMZELX® (bim zel' ex)
(bimekizumab-bkzx)
injection, for subcutaneous use
single-dose autoinjector

This Instructions for Use contains information on how to inject BIMZELX.

Read this Instructions for Use before using the BIMZELX autoinjector 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 treatment.

These instructions are for 1 injection only. You may need more than 1 injection at a time depending on your prescribed dose of BIMZELX. Each BIMZELX autoinjector is for one-time (single-dose) use only.

Important Information you Need to Know Before Injecting BIMZELX:

- Your healthcare provider should show you or a caregiver how to prepare and inject BIMZELX using the autoinjector for the first time. Do not inject yourself or someone else until you have been shown how to inject BIMZELX the right way. Call your healthcare provider if you have any questions.
- These instructions are for 1 injection only.
- The BIMZELX autoinjector has a needle safety feature that will be activated to cover the needle after the injection is finished. The needle safety feature will help to prevent needle stick injuries to anyone who handles the autoinjector after injection.
- **Do not** share or reuse your BIMZELX autoinjector. You may give or get an infection.
- **Do not** remove the needle cap until just before you give the injection.
- If you have vision or hearing problems, **do not** use the BIMZELX autoinjector without help from a caregiver.

How should I store BIMZELX autoinjector?

- Store the BIMZELX autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- BIMZELX autoinjectors may be stored at room temperature up to 77°F (25°C) in the original carton for up to 30 days. **Do not** place BIMZELX autoinjectors back in the refrigerator after they have been stored at room temperature.
- Write the date removed from the refrigerator in the space provided on the carton and throw away if it has been kept at room temperature and not used within 30 days.
- Keep BIMZELX in the original carton until ready for use to protect from light.
- Do not freeze BIMZELX.
- Do not shake BIMZELX.
- Do not use the BIMZELX autoinjector past the expiration date printed on the carton.

Keep BIMZELX autoinjectors and all medicines out of the reach of children.

BIMZELX autoinjector parts (see Figure A):

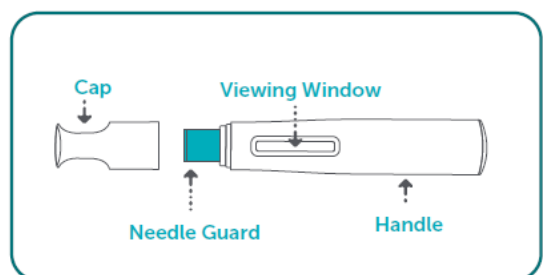


Figure A

Supplies Needed for each BIMZELX injection

- 1 BIMZELX autoinjector. You may need 2 BIMZELX autoinjectors to give the prescribed dose.

Not provided in the BIMZELX autoinjector carton:

- 1 alcohol swab
- 1 clean cotton ball
- 1 sharps disposal container. See, “**Step 12: Dispose of (throw away) the used BIMZELX autoinjector**” at the end of this Instructions for Use.

Setting up for your BIMZELX injection.

Step 1: Take the BIMZELX autoinjector carton out of the refrigerator. Do not use the BIMZELX autoinjector(s) if the carton seal is broken. Throw it away and get a new one.

- **Keep the BIMZELX autoinjector in its original carton for 30 to 45 minutes** to warm to room temperature. This will help to reduce discomfort when injecting.
 - **Do not** microwave the autoinjector, run hot water over it, or leave it in direct sunlight.
 - **Do not** shake the autoinjector.
 - **Do not** take the cap off the autoinjector until you are ready to inject.

Step 2: Find a clean, flat, and well-lit work surface, like a table.

Step 3: Gather the supplies needed for your injection.

Step 4: Wash your hands well with soap and water and dry with a clean towel.

Step 5: Inspect the BIMZELX autoinjector (see **Figure B**):

- Remove the BIMZELX autoinjector from the carton.
- **Make sure the name BIMZELX appears on the label.**
 - Check the expiration date printed on the label.
 - Check the medicine through the Viewing Window. The medicine inside should be clear to slightly pearly, and colorless to pale brownish-yellow. You may see air bubble(s) in the liquid. This is normal.
- **Do not use the BIMZELX autoinjector**, throw it away and get a new one if:
 - The expiration date printed on the label has passed.
 - The medicine is cloudy, discolored, or has particles.
 - It looks damaged or has been dropped.

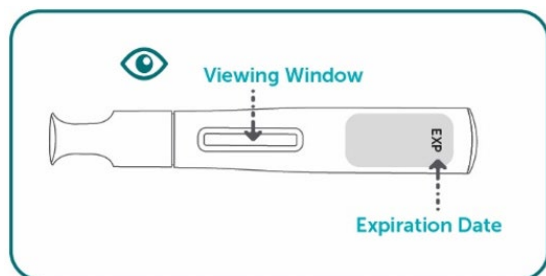


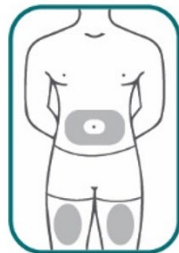
Figure B

Choose and prepare your injection site.

Step 6: Choose and clean your injection site.

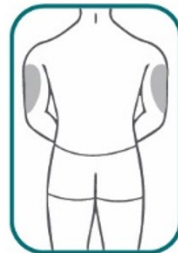
- **The sites you may choose for your injection are:**
 - your stomach area (abdomen) or your thigh (see **Figure C**).

- the back of your arm (**see Figure D**). BIMZELX may be injected into the back of your arm by a healthcare provider or caregiver only.



Abdomen or thigh

Figure C



Back of arm

Figure D

- **Do not** inject into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis, or within 2 inches of the belly button (navel).
- Choose a new injection site on the body each time you use BIMZELX. **Do not** use the same injection site 2 times in a row.

Step 7: Prepare your skin

- Clean the injection site with an alcohol swab. Let the area dry completely. **Do not** touch the cleaned area again before injecting.

Injecting BIMZELX.

Step 8: Remove the BIMZELX autoinjector cap.

- Hold the BIMZELX autoinjector firmly with one hand around the handle. Pull the cap straight off (away from) the autoinjector with the other hand (**see Figure E**). Although you cannot see the needle tip, it is now uncovered.
 - **Put** the cap into an FDA-cleared sharps disposal container right away. You will not need it again.
 - **Do not** touch the needle guard or put the cap back on as it could activate the autoinjector and you can stick yourself.

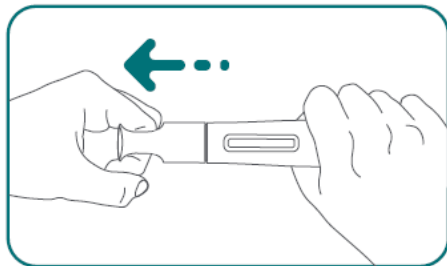


Figure E

Step 9: Hold the BIMZELX autoinjector at a 90-degree angle to the cleaned injection site (**see Figure F**).

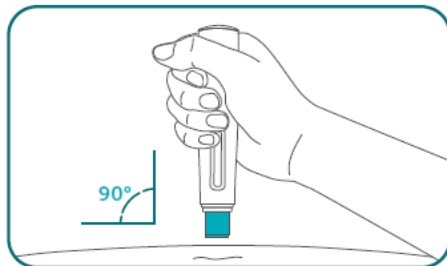


Figure F

Step 10: Place the BIMZELX autoinjector flat against your skin, then firmly press the BIMZELX autoinjector down against your skin. **You will hear a “click” sound.** Your injection begins when the 1st “click” is heard (**see Figure G**).

- **Do not** lift the autoinjector away from the skin.

Keep holding the BIMZELX autoinjector in place and pressed firmly against your skin. It will take about 15 seconds to receive your full dose.

- You will hear a 2nd “click” in about 15 seconds after you hear the first click.
- The second click tells you that all the medicine has been injected and your BIMZELX injection is finished. You should see the yellow color indicator filling the viewing window (**see Figure H**).
- **Important:** When you remove the autoinjector, if the viewing window has not turned yellow this means you may not have received a full dose. Call your healthcare provider right away.

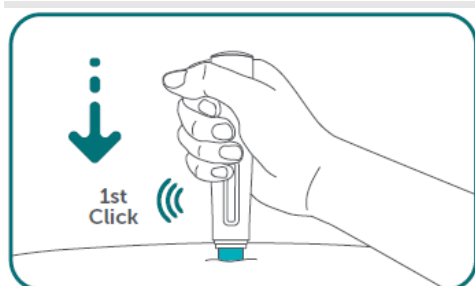


Figure G

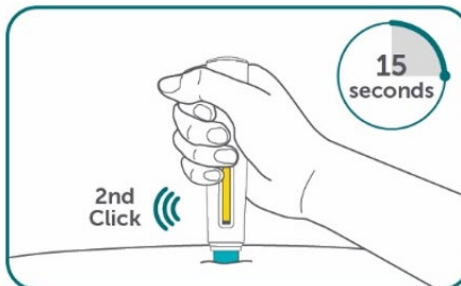


Figure H

Step 11: Remove the BIMZELX autoinjector by carefully pulling the BIMZELX autoinjector straight up from your skin. The needle guard will automatically cover the needle. **Do not** try to touch the needle.

- Press a clean cotton ball over the injection site for a few seconds. **Do not** rub the injection site. You may see slight bleeding or a drop of liquid. This is normal. You may cover the injection site with a small adhesive bandage, if needed.

Step 12: Dispose of (throw away) the used BIMZELX autoinjector (see Figure I).

- Put the used BIMZELX autoinjector in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the BIMZELX autoinjector in your household trash. 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 needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA’s website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** recycle your used sharps disposal container.

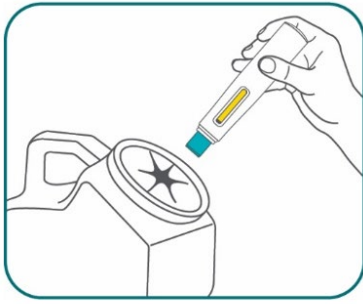


Figure I

Step 13: Repeat steps 1 through 12 with a new BIMZELX autoinjector if you need to use 2 autoinjectors to give the prescribed dose.

- Make sure you select a new injection site on the body each time you use BIMZELX. **Do not** use the same site that you used for your first injection.

You can sign up to receive sharps containers for BIMZELX autoinjector disposal at no additional cost by going to www.BIMZELX.com or call 1-844-599-2273.

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

Issued: 9/2024