



INSTRUCTIONS FOR USE

BIMZELX[®] (bim zel' ex)
(bimekizumab-bkzx)

**INJECTION, FOR
SUBCUTANEOUS USE**

**320 mg/2 mL
single-dose
autoinjector**

Indication: BIMZELX[®] is a prescription medicine used to treat adults with moderate-to-severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet light alone or with pills (phototherapy), adults with active psoriatic arthritis, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation, adults with active ankylosing spondylitis, and adults with moderate-to-severe hidradenitis suppurativa.

Important Safety Information: Suicidal thoughts and behavior have happened in some people treated with BIMZELX. Get medical help right away or call the National Suicide and Crisis Lifeline at 988 if you, your caregiver, or your family member notice any of these symptoms.

Please see accompanying full [Prescribing Information](#) and [Medication Guide](#).

 **Bimzelx[®]**
(bimekizumab-bkzx)



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.

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 before 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 as 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.

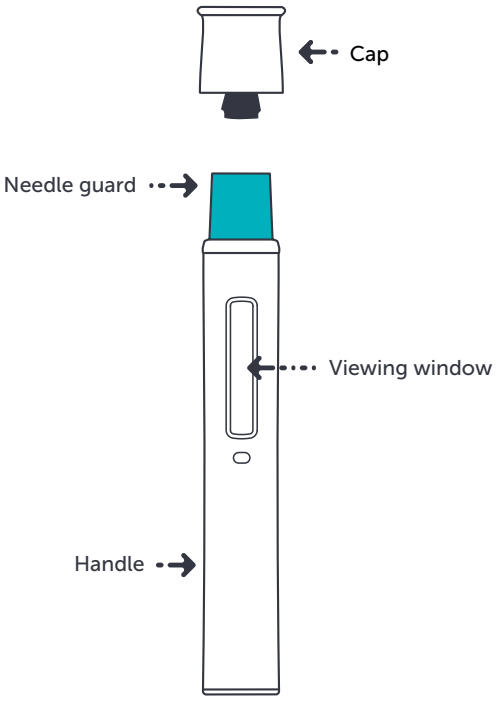
Keep BIMZELX autoinjectors and all medicines out of the reach of children.

BIMZELX[®]

AUTOINJECTOR PARTS

(SEE FIGURE A):

Figure A



SUPPLIES NEEDED FOR EACH BIMZELX INJECTION

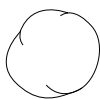


1 BIMZELX autoinjector

**Not provided in the BIMZELX
autoinjector carton:**



1 alcohol swab



1 clean cotton ball

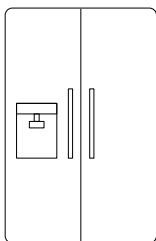


**1 sharps disposal
container. See "Step 12:
Dispose of (throw away)
the used BIMZELX
autoinjector" at the end
of this Instructions for Use.**

SETTING UP FOR YOUR BIMZELX[®] INJECTION

> STEP 1

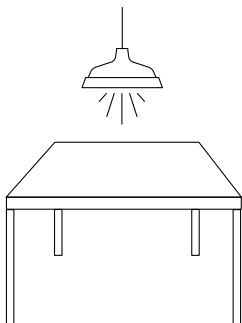
Take the BIMZELX autoinjector carton out of the refrigerator. Do not use the BIMZELX autoinjector(s) if the carton seal is broken. Throw it away and get a new one.



- 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.

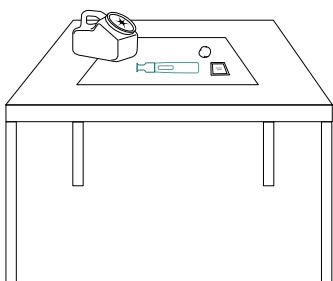
> STEP 2

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



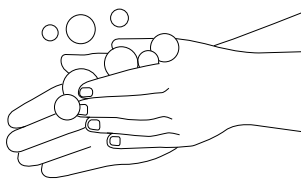
> STEP 3

Gather the supplies needed for your injection.



> STEP 4

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



SETTING UP FOR YOUR BIMZELX® INJECTION

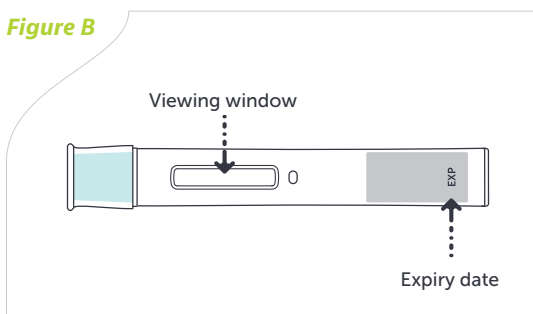
(CONT'D)

> 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; or
 - it looks damaged or has been dropped.

Figure B



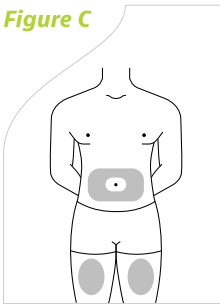
CHOOSE AND PREPARE YOUR INJECTION SITE

> STEP 6

Choose and clean your injection site.

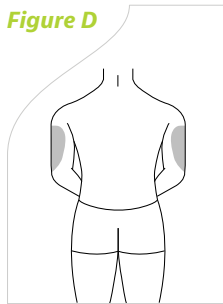
- The sites you may choose for your injection are:
 - Your stomach area (abdomen) or your thigh (see Figure C).
 - The back of your arm (see Figure D). BIMZELX may be injected into the back of your arm by a healthcare provider or caregiver only.

Figure C



Abdomen or thigh

Figure D



Back of arm

- **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).
- You should change (rotate) your injection site with each injection. **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.

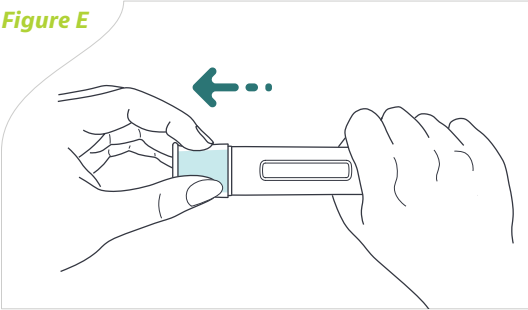
INJECTING BIMZELX

> 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 the cap again.
 - **Do not** touch the needle guard or put the cap back on, as this could activate the autoinjector and cause you to stick yourself.

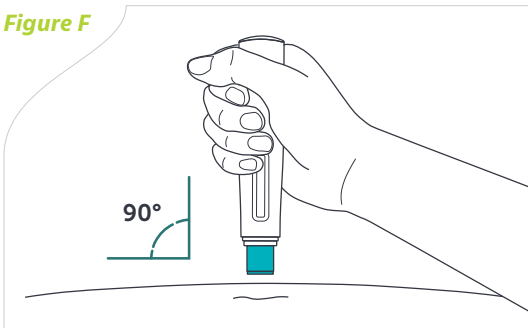
Figure E



> STEP 9

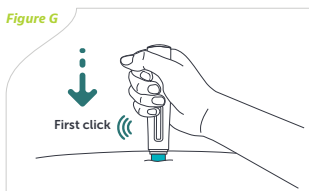
Hold the BIMZELX autoinjector at a 90-degree angle to the cleaned injection site (see Figure F).

Figure F



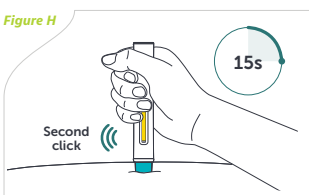
> STEP 10

Place the BIMZELX autoinjector flat against your skin and 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.

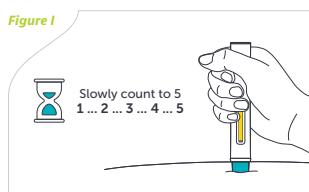
↓ **HOLD**



Keep holding the BIMZELX autoinjector in place and pressed firmly against your skin. It will take about 20 seconds to receive your full dose.

- You will hear a 2nd “click” in about 20 seconds after you hear the first click.
- The second click tells you the injection is almost complete. You should see the yellow color indicator filling the viewing window (see Figure H).

↓ **HOLD**



- After the 2nd click, continue to hold down the BIMZELX autoinjector for an additional 5 seconds (slowly count to 5). This will ensure you receive your full dose (see Figure I).

- **Important:** When you remove the autoinjector, if the viewing window has not turned yellow, you may not have received a full dose. Call your healthcare provider right away.

> 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. If needed, you may cover the injection site with a small adhesive bandage.

> STEP 12

Dispose of (throw away) the used BIMZELX autoinjector (see Figure J).

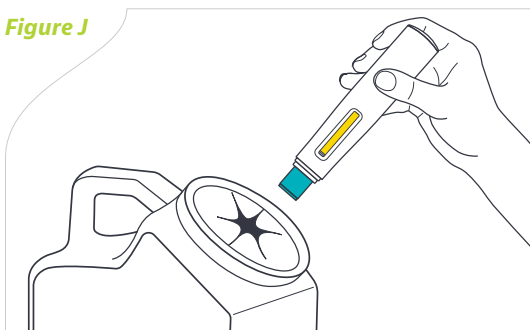
- Put the used BIMZELX autoinjector in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the BIMZELX autoinjector in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - 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.

INJECTING BIMZELX

(CONT'D)

- 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 your state, go to the FDA website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** recycle your used sharps disposal container.

Figure J



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

Manufactured by:
UCB, Inc., 1950 Lake Park Drive, Smyrna, GA 30080
US License No. 1736

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

Issued: 10/2024

Indication: BIMZELX® is a prescription medicine used to treat adults with moderate-to-severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet light alone or with pills (phototherapy), adults with active psoriatic arthritis, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation, adults with active ankylosing spondylitis, and adults with moderate-to-severe hidradenitis suppurativa.

Important Safety Information: Suicidal thoughts and behavior have happened in some people treated with BIMZELX. Get medical help right away or call the National Suicide and Crisis Lifeline at 988 if you, your caregiver, or your family member notice any of these symptoms.

BIMZELX affects the immune system. It may increase your risk of infections, which can be serious. Do not use BIMZELX if you have any symptoms of infection without talking to your doctor. If you have any symptoms of infection after starting BIMZELX, call your doctor right away.

 **Bimzelx**®
(bimekizumab-bkzx)



Inspired by patients.

Driven by science.

BIMZELX® is made by UCB, a global biopharmaceutical company. UCB is passionate about helping patients and their families with chronic severe diseases.

BIMZELX® is a registered trademark of the UCB Group of Companies.

©2024 UCB, Inc., Smyrna, GA 30080. All rights reserved.
US-BK-2401528