



INSTRUCTIONS FOR USE

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

**INJECTION, FOR
SUBCUTANEOUS USE**

***320 mg/2 mL
single-dose
prefilled syringe***

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 prefilled syringe 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 prefilled syringe 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 prefilled syringe 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 prefilled syringe 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 prefilled syringe after injection.
- **Do not** share or reuse your BIMZELX prefilled syringe as you may give or get an infection.
- **Do not** remove the needle cap until just before you give the injection.

How should I store BIMZELX prefilled syringe?

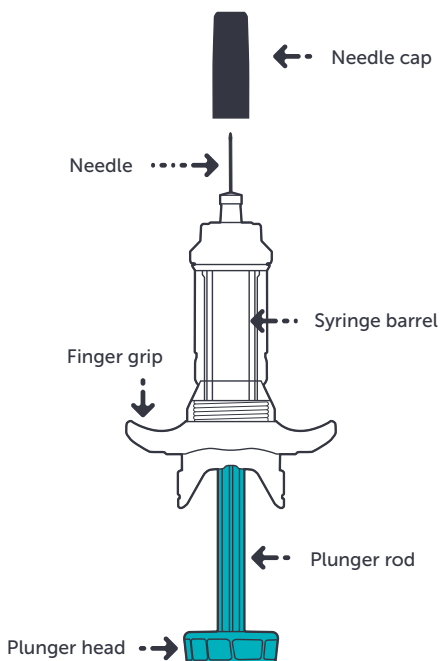
- Store the BIMZELX prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- BIMZELX prefilled syringes may be stored at room temperature up to 77°F (25°C) in the original carton for up to 30 days. Do not place BIMZELX prefilled syringes back in the refrigerator after they have been 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 the BIMZELX prefilled syringe 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 prefilled syringe past the expiration date printed on the carton.

Keep BIMZELX prefilled syringes and all medicines out of the reach of children.

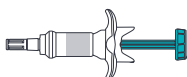
BIMZELX[®] PREFILLED SYRINGE PARTS

(SEE FIGURE A):

Figure A



SUPPLIES NEEDED FOR EACH BIMZELX INJECTION:



**1 BIMZELX
prefilled syringe**

**Not provided in the BIMZELX
prefilled syringe carton:**



1 alcohol swab



1 clean cotton ball

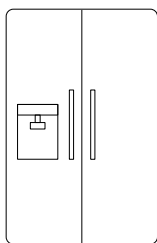


**1 sharps disposal
container. See "Step
12: Dispose of (throw
away) the used BIMZELX
prefilled syringe" at the
end of this Instructions
for Use.**

SETTING UP FOR YOUR BIMZELX[®] INJECTION

> STEP 1

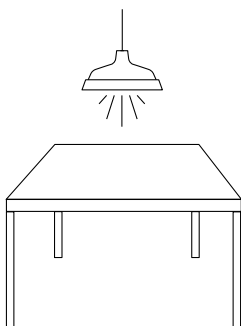
Take the BIMZELX prefilled syringe carton out of the refrigerator. Do not use the BIMZELX prefilled syringe(s) if the carton seal is broken. Throw it away and get a new one.



- Keep the BIMZELX prefilled syringe 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 prefilled syringe, run hot water over it, or leave it in direct sunlight.
 - **Do not** shake the prefilled syringe.
 - **Do not** take the cap off the prefilled syringe until you are ready to inject.

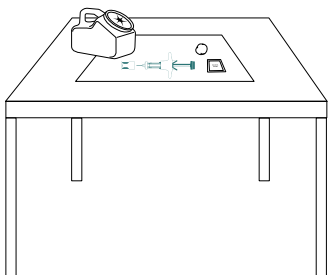
> STEP 2

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



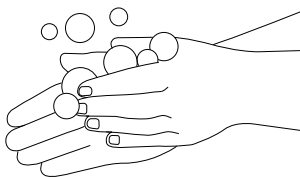
> STEP 3

Gather the supplies 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

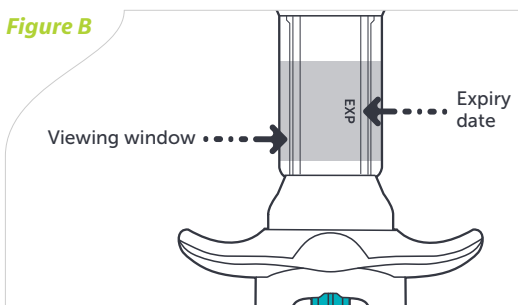
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> STEP 5

Inspect the BIMZELX prefilled syringe (see Figure B):

- Remove the BIMZELX prefilled syringe 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 prefilled syringe, 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



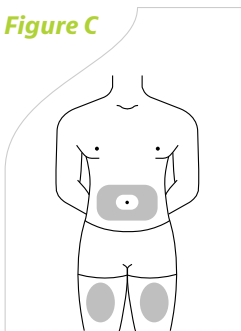
CHOOSE AND PREPARE YOUR INJECTION SITE

> STEP 6

Choose and clean your injection site.

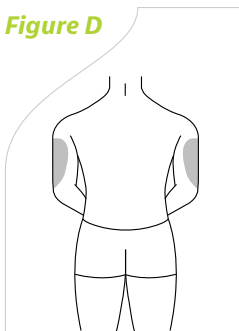
- The sites you may choose for your injection are:
 - your stomach area (abdomen) or in your thigh (see Figure C).
 - the back of your arm (see Figure D). BIMZELX may be injected into the back of your arm by a healthcare provider or caregiver only.

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.

CHOOSE AND PREPARE YOUR INJECTION SITE

(CONT'D)

> 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.

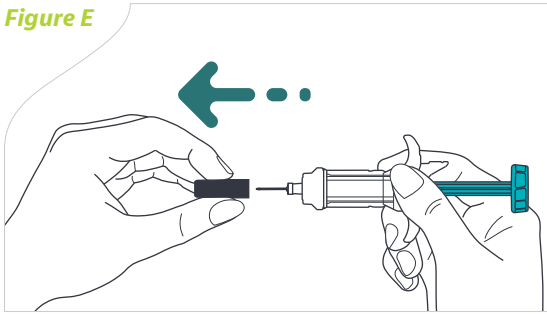
INJECTING BIMZELX[®]

> STEP 8

Remove the BIMZELX prefilled syringe needle cap.

- Hold the BIMZELX prefilled syringe around the finger grip with one hand. Pull the cap straight off (away from) the BIMZELX prefilled syringe with the other hand (see **Figure E**). You may see a drop of liquid on the tip of the needle. This is normal.
 - **Put** the cap into an FDA-cleared sharps disposal container right away. You will not need it again.
 - **Do not** touch the needle or let the needle touch any surface.
 - **Do not** hold the plunger rod during cap removal. If you accidentally remove the plunger rod, throw the BIMZELX prefilled syringe away and call your healthcare provider.
 - **Do not** put the needle cap back on.

Figure E



> STEP 9

Gently pinch and hold a fold of skin where you cleaned the injection site with one hand. With the other hand, insert the needle into your skin at about a 45-degree angle.

- Push the needle all the way in to make sure that you inject your full dose. Then gently let go of your skin. Make sure the needle is in place (see Figure F).

Figure F



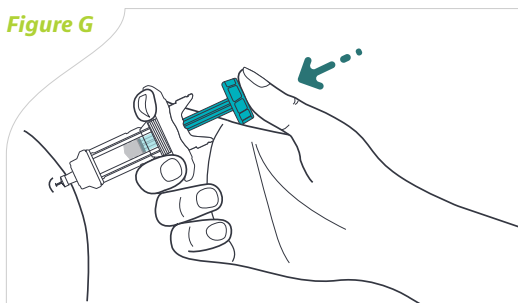
INJECTING BIMZELX[®]

(CONT'D)

> STEP 10

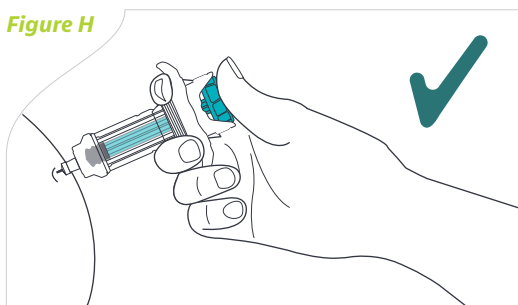
Firmly push the plunger head all the way down until all the medicine is injected (see Figure G).

Figure G



- All the medicine is injected when you cannot push the plunger head any further (see Figure H).

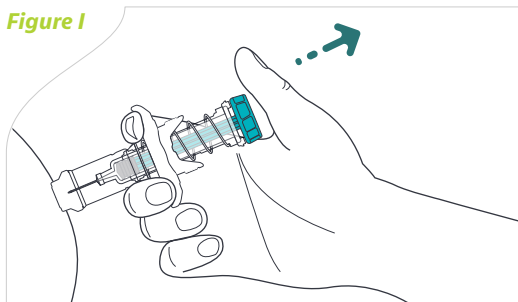
Figure H



> STEP 11

Lift your thumb off the plunger head (see Figure I). The needle will automatically move back in and lock in place.

Figure I



- Press a clean cotton ball or gauze pad 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 prefilled syringe (see Figure J).

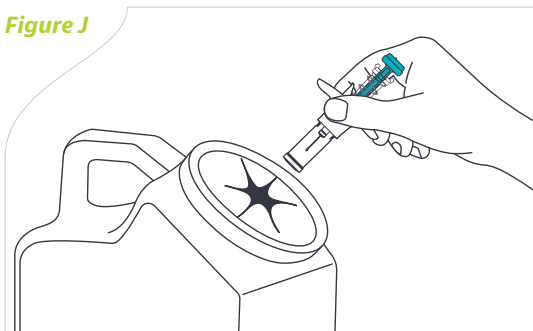
- Put the used BIMZELX prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the BIMZELX prefilled syringe in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: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

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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.

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