

INSTRUCTIONS FOR USE

BIMZELX[®]▼ (BIM ZEL' EX) (BIMEKIZUMAB) SOLUTION FOR SUBCUTANEOUS USE

Indication: BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Report adverse events: Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk and hpra.ie/homepage/about-us/report-an-issue. Adverse events should also be reported to UCB Pharma Ltd Email: UCBCares.UK@ucb.com and UCBCares.IE@ucb.com.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See [local reporting information](#), e.g. signpost to <https://yellowcard.mhra.gov.uk> for UK.

WELCOME TO A NEW START WITH BIMZELX[®]

Your doctor has prescribed **BIMZELX[®]** and now it's time for the next step in treating your moderate to severe plaque psoriasis.

Patient support is available to you as soon as you've been prescribed BIMZELX. UCBCares[®] is a personalised service that is here to support you and answer questions you may have about your BIMZELX treatment or the support materials available.

Here is how you can reach us:

[\[Regional contact info\]](#)

TABLE OF CONTENTS

- **Important Safety Information**
- **BIMZELX® Device Parts**
- **Setting Up For Your BIMZELX® Injections**
- **Choose and Prepare Your Injection Site**
- **Inject BIMZELX®**
- **Disposing of Your Injection**





INSTRUCTIONS FOR USE

**BIMZELX[®] (BIM ZEL' EX)
(BIMEKIZUMAB) SOLUTION
FOR SUBCUTANEOUS USE**

Pre-filled Pen

Indication: BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

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Please read these **Instructions for Use** before using the BIMZELX pre-filled pen and each time you get a refill. There may be new information.

IMPORTANT INFORMATION:

- Your healthcare professional should show you how to prepare and inject BIMZELX using the pre-filled pen.
Do not inject yourself or someone else until you have been shown how to inject BIMZELX the right way.
- You and/or your caregiver should read these Instructions for Use before each use of BIMZELX.
- Call your healthcare professional if you or your caregiver have any questions about how to inject BIMZELX the right way.
- **To receive your full dose, you will need to use 2 BIMZELX pre-filled pens, one after the other.**

Do not use this medicine and return it to the pharmacy if:

- the expiry date (EXP) has passed.
- the carton seal is broken.
- the pre-filled pen has been dropped or looks damaged.
- the liquid has ever been frozen (even if thawed).

Keep BIMZELX® out of the sight and reach of children.

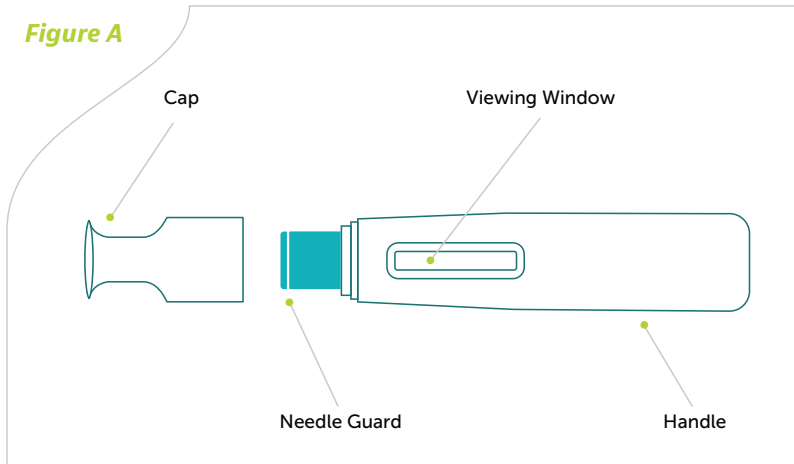
For a more comfortable injection:

- Take the BIMZELX pre-filled pens out of the refrigerator and let them sit on a flat surface at room temperature for **30 to 45 minutes** before injecting.
- Do not warm in any other way, such as in a microwave or in hot water.
- Do not shake the pre-filled pens.
- Do not uncap the pre-filled pens until you are ready to inject.

<Local markets to insert Rules and Regulations appropriate to their market here>
These Instructions for Use are for people prescribed BIMZELX only. Please see the BIMZELX 'Package Leaflet: Information for the user' for additional information.

BIMZELX PRE-FILLED PEN PARTS

(SEE FIGURE A):

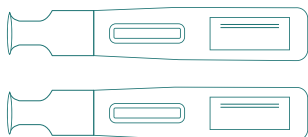


*Call your healthcare professional or
(866) BIMZELX or **(866) 123-4567** if you
need help or do not know how to proceed.*

> STEP 1: SETTING UP FOR YOUR BIMZELX INJECTIONS

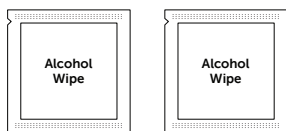
Follow the steps below each time you use BIMZELX.

Place the following items on a clean, flat, well-lit work surface, like a table:

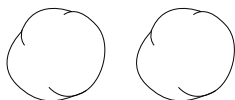


2 BIMZELX pre-filled pens

Items not provided in the BIMZELX® pre-filled pen carton:



2 alcohol wipes



2 clean cotton balls



1 sharps disposal container
(i.e. a puncture-resistant closable container, or similar)

> Contact your healthcare provider's office or a pharmacy if you need a sharps container and have not been given one yet.

Start with one pre-filled pen for the first injection. For the full dose, 2 injections are required, one after the other.

> STEP 2: CHOOSE AND PREPARE YOUR INJECTION SITE

2a: Choose your injection site.

- The places you may choose for your injection are:
 - your stomach area (abdomen) or your thigh (see Figure B).
 - the back of your arm may also be used if a caregiver is giving you the injection (see Figure C).

Figure B

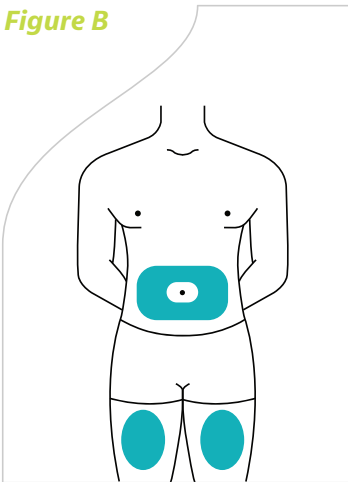
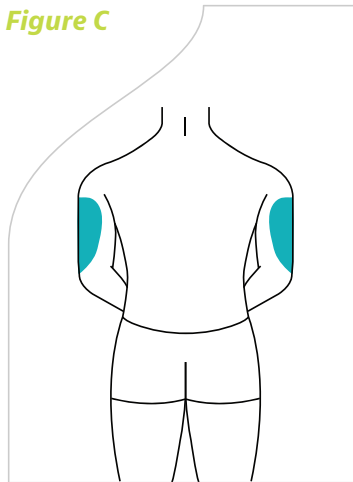


Figure C



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly button (navel).
- You should use a different place for each injection. Do not use the same place to inject twice in a row.

2b: Wash your hands well with soap and water and dry with a clean towel.

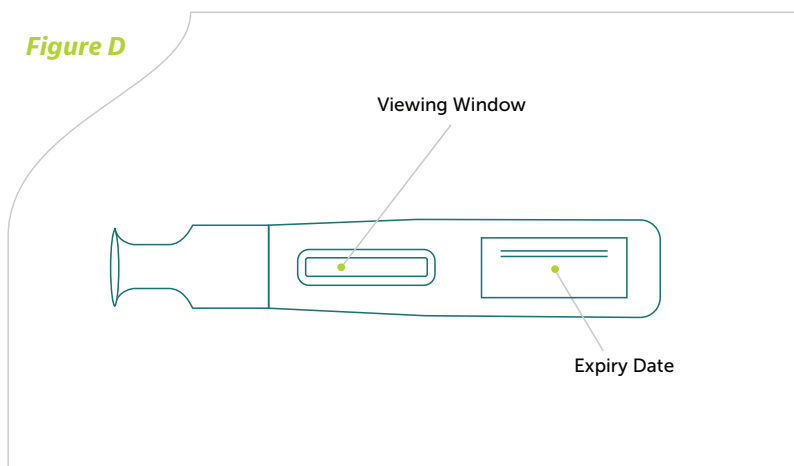
2c: Prepare your skin.

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

2d: Check the pre-filled pen (see Figure D).

- Make sure the name BIMZELX and expiry date appear on the label.
- Check the medicine through the viewing window. The medicine should be clear to slightly opalescent and free of particles. Its colour may vary from colourless to pale brownish-yellow. You may see air bubbles in the liquid. This is normal.
- Do not use the BIMZELX pre-filled pen if the medicine is cloudy, discoloured, or has particles. **[Contact your pharmacy to report the issue].**

Figure D

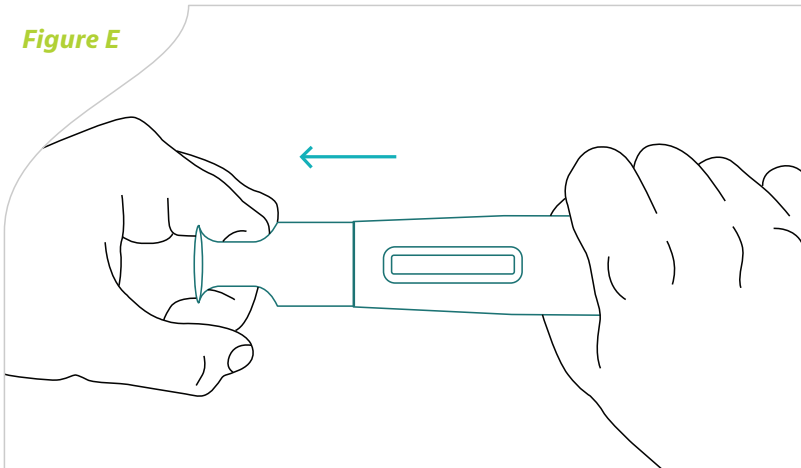


> STEP 3: INJECT BIMZELX

3a: Remove the pre-filled pen cap

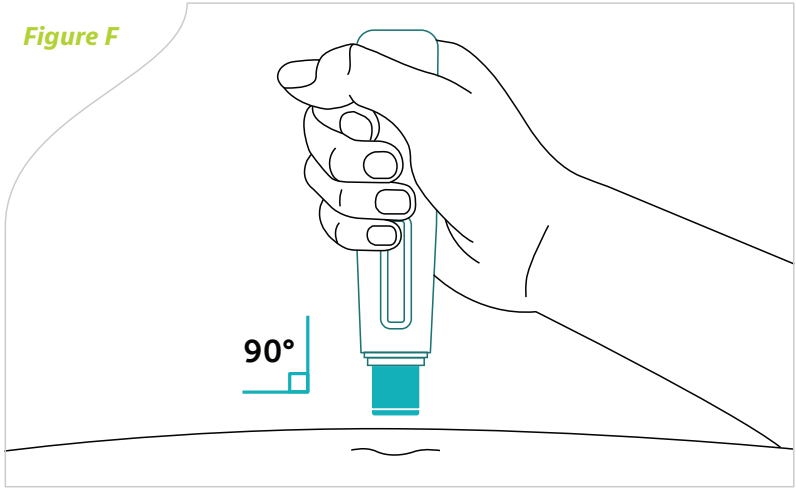
- Hold the pre-filled pen firmly with one hand. Pull the cap straight off the pre-filled pen with the other hand (see Figure E). Although you cannot see the needle tip, it is now uncovered.
 - Do not touch the needle guard or put the cap back on. This is because it could activate the pre-filled pen and you could prick yourself.

Figure E



3b: Hold the pre-filled pen at a 90 degree angle to the cleaned injection site (see Figure F).

Figure F

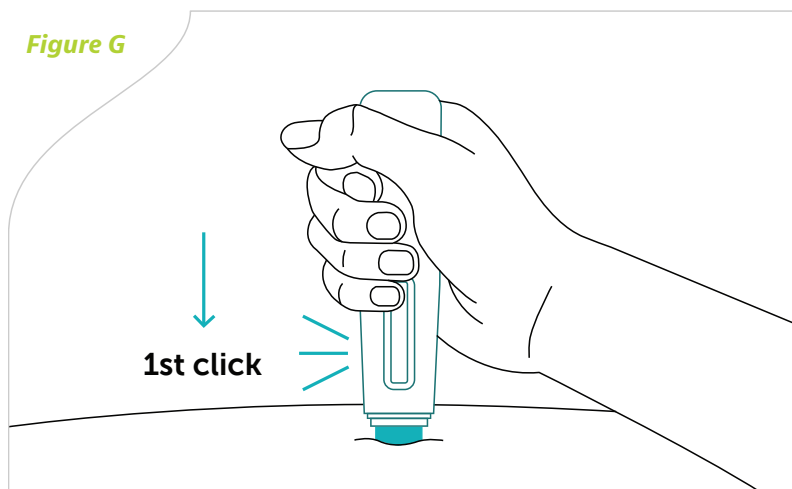


> STEP 3: INJECT BIMZELX

3c: Place the pre-filled pen flat against your skin, then firmly press the pre-filled pen down against your skin.

- You will hear a click sound. Your injection begins when the first “click” is heard (see Figure G).
- **Do not lift the pre-filled pen away from the skin.**

Figure G



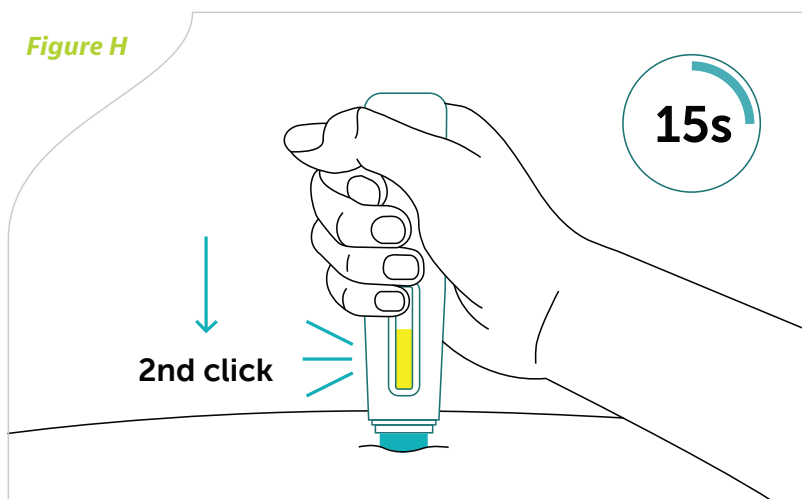
3d: Keep holding the pre-filled pen in place and pressed firmly against your skin.

- You will hear a second “click” within about 15 seconds after 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 colour indicator filling the viewing window (see Figure H).

If there is no second “click”, or the full amount of liquid was not injected, please contact your doctor or pharmacist. Do not try to repeat the injection process without speaking to your doctor or pharmacist.

Figure H



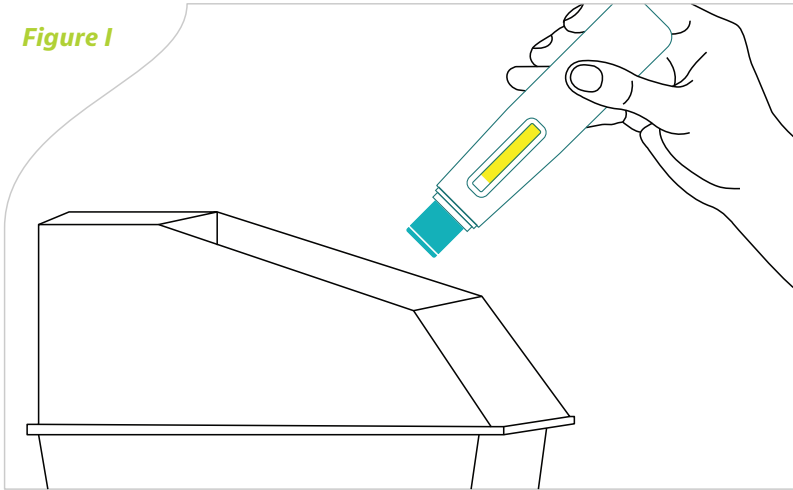
3e: Remove the pre-filled pen by carefully pulling it straight up from your skin. The needle guard will automatically cover the needle.

- Press a dry 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 **plaster**, if needed.

> STEP 4: DISPOSING OF YOUR INJECTION

Put the used pre-filled pen in a sharps disposal container straight away after use (see Figure I).

Figure I



For the second injection of your prescribed dose, use a new BIMZELX pre-filled pen and repeat steps 2 to 4.

Make sure to select a new injection site for your second injection.



INSTRUCTIONS FOR USE

**BIMZELX[®] (BIM ZEL' EX)
(BIMEKIZUMAB) SOLUTION
FOR SUBCUTANEOUS USE**

Pre-filled Syringe

Indication: BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Report adverse events: Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk and hpra.ie/homepage/about-us/report-an-issue. Adverse events should also be reported to UCB Pharma Ltd Email: UCBCares.UK@ucb.com and UCBCares.IE@ucb.com.



Please read these **Instructions for Use** before using the BIMZELX pre-filled syringe and each time you get a refill. There may be new information.

IMPORTANT INFORMATION:

- Your healthcare professional should show you how to prepare and inject BIMZELX using the pre-filled syringe. **Do not** inject yourself or someone else until you have been shown how to inject BIMZELX the right way.
- You and/or your caregiver should read these Instructions for Use before each use of BIMZELX.
- Call your healthcare professional if you or your caregiver have any questions about how to inject BIMZELX the right way.
- **To receive your full dose, you will need to use 2 BIMZELX pre-filled syringes, one after the other.**
- The BIMZELX pre-filled syringe has a needle safety feature. This will cover the needle automatically after the injection is finished. The needle safety feature will help to prevent needle injury to anyone who handles the pre-filled syringe after injection.

Do not use this medicine and return it to the pharmacy if:

- the expiry date (EXP) has passed.
- the carton seal is broken.
- the pre-filled syringe has been dropped or looks damaged.
- the liquid has ever been frozen (even if thawed).

Keep BIMZELX® out of the sight and reach of children.

For a more comfortable injection:

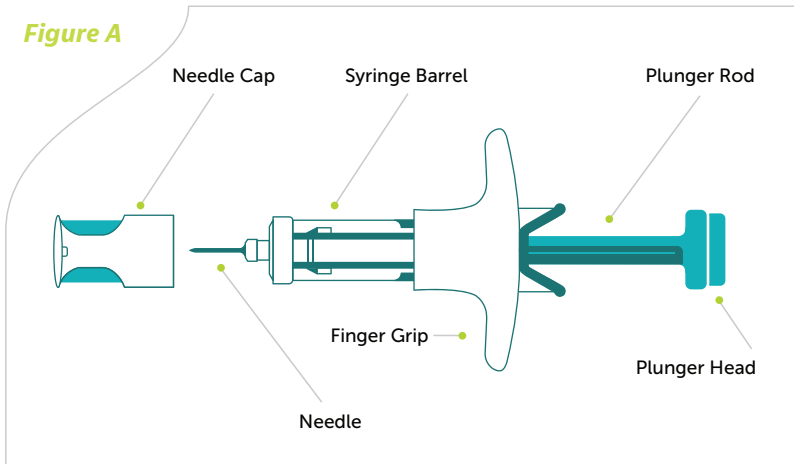
- Take the BIMZELX pre-filled syringes out of the refrigerator and let them sit on a flat surface at room temperature for **30 to 45 minutes** before injecting.
- Do not warm in any other way, such as in a microwave or in hot water.
- Do not shake the pre-filled syringes.
- Do not uncap the pre-filled syringes until you are ready to inject.

<Local markets to insert Rules and Regulations appropriate to their market here>

These Instructions for Use are for people prescribed BIMZELX only. Please see the BIMZELX 'Package Leaflet: Information for the user' for additional information.

BIMZELX PRE-FILLED SYRINGE PARTS

(SEE FIGURE A):

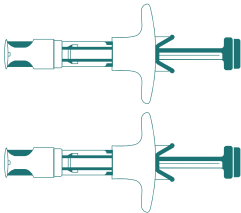


*Call your healthcare professional or
(866) BIMZELX or **(866) 123-4567** if you
need help or do not know how to proceed.*

> STEP 1: SETTING UP FOR YOUR BIMZELX INJECTIONS

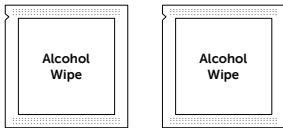
Follow the steps below each time you use BIMZELX.

Place the following items on a clean, flat, well-lit work surface, like a table:

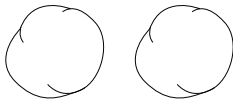


2 BIMZELX pre-filled syringes

Items not provided in the BIMZELX® pre-filled syringe carton:



2 alcohol wipes



2 clean cotton balls



1 sharps disposal container
(i.e. a puncture-resistant closable container, or similar)

> Contact your healthcare provider's office or a pharmacy if you need a sharps container and have not been given one yet.

Start with one pre-filled syringe for the first injection. For the full dose, 2 injections are required, one after the other.

> STEP 2: CHOOSE AND PREPARE YOUR INJECTION SITE

2a: Choose your injection site.

- The places you may choose for your injection are:
 - your stomach area (abdomen) or your thigh (see **Figure B**).
 - the back of your arm may also be used if a caregiver is giving you the injection (see **Figure C**).

Figure B

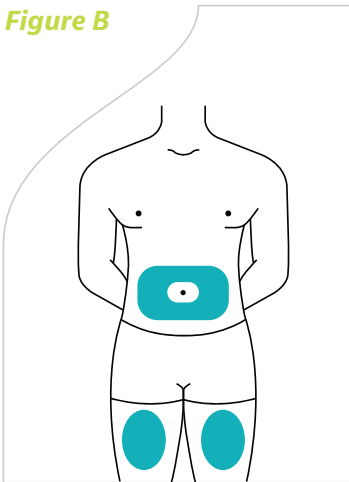
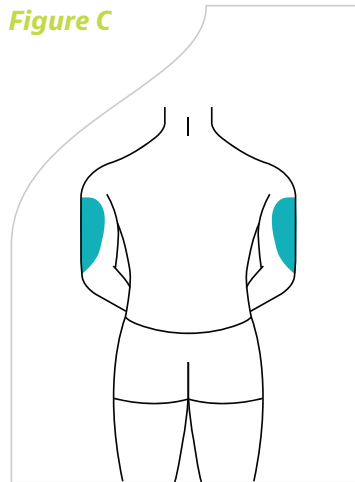


Figure C



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly button (navel).
- You should use a different place for each injection. Do not use the same place to inject twice in a row.

2b: Wash your hands well with soap and water and dry with a clean towel.

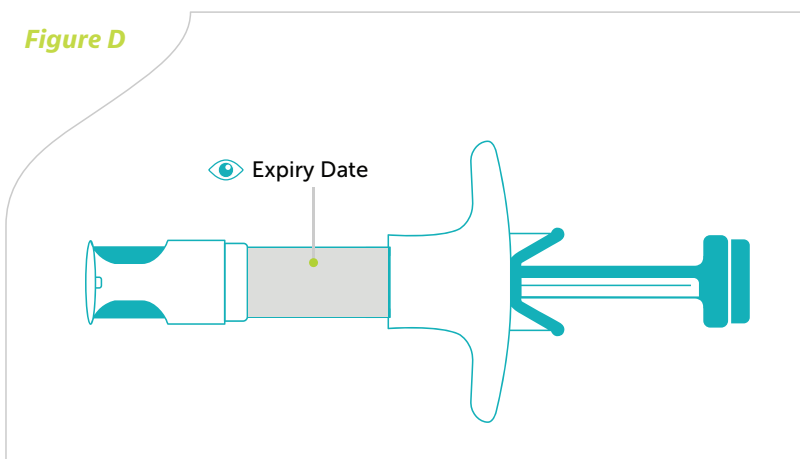
2c: Prepare your skin.

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

2d: Check the pre-filled syringe (see Figure D).

- Make sure the name BIMZELX and expiry date appear on the label.
- Check the medicine through the viewing window. The medicine should be clear to slightly opalescent and free of particles. Its colour may vary from colourless to pale brownish-yellow. This is normal.
- Do not use the BIMZELX pre-filled syringe if the medicine is cloudy, discoloured, or has particles. **[Contact your pharmacy to report the issue].**

Figure D

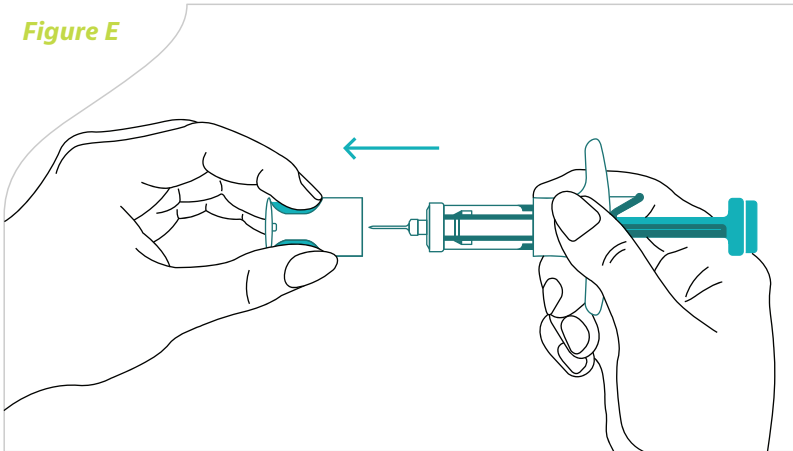


> STEP 3: INJECT BIMZELX

3a: Remove the pre-filled syringe needle cap

- Hold the pre-filled syringe around the finger grip with one hand. Pull the cap straight off the pre-filled syringe with the other hand (see Figure E). You may see a drop of liquid on the tip of the needle. This is normal.
 - **Do not** touch the needle or let the needle touch any surface.
 - **Do not** hold the plunger rod when you remove the cap. If you accidentally remove the plunger rod, throw the pre-filled syringe in the sharps disposal container and get a new one.
 - **Do not** put the needle cap back on. If you do, you could damage the needle or prick yourself by accident.

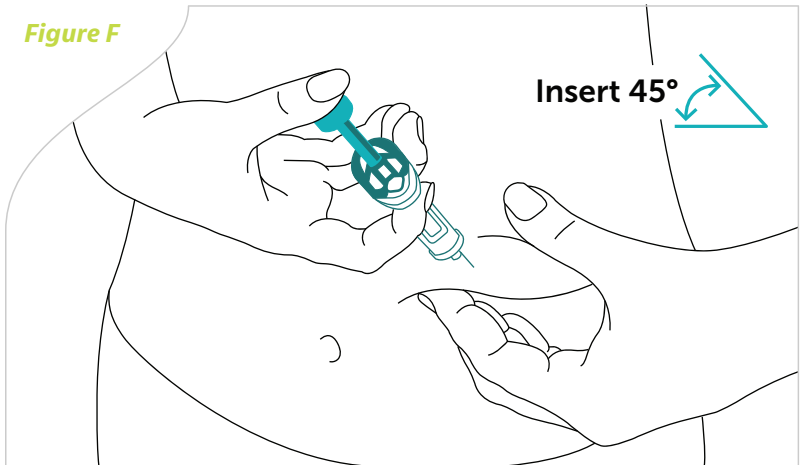
Figure E



3b: Gently pinch and hold with one hand a fold of skin that you cleaned for the injection. With the other hand, insert the needle into your skin at about a 45 degree angle.

- Push the needle all the way in. Then gently let go of your skin. Make sure the needle is in place (see Figure F).

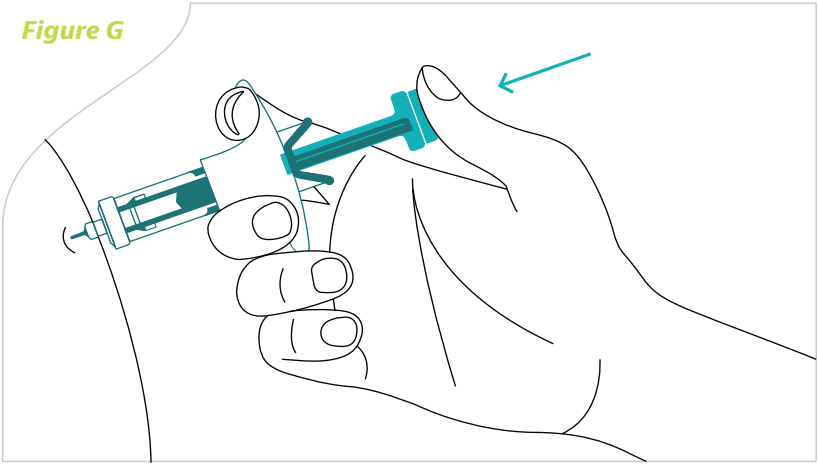
Figure F



> STEP 3: INJECT BIMZELX

3c: Firmly push the plunger head all the way down until all the medicine is injected (see Figure G).

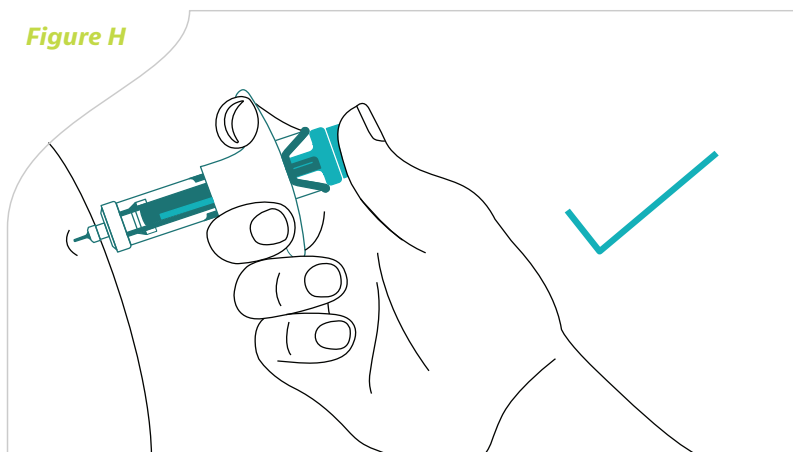
Figure G



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

If you believe all the medicine was not injected, please contact your doctor or pharmacist. Do not try to repeat the injection process without speaking to your doctor or pharmacist.

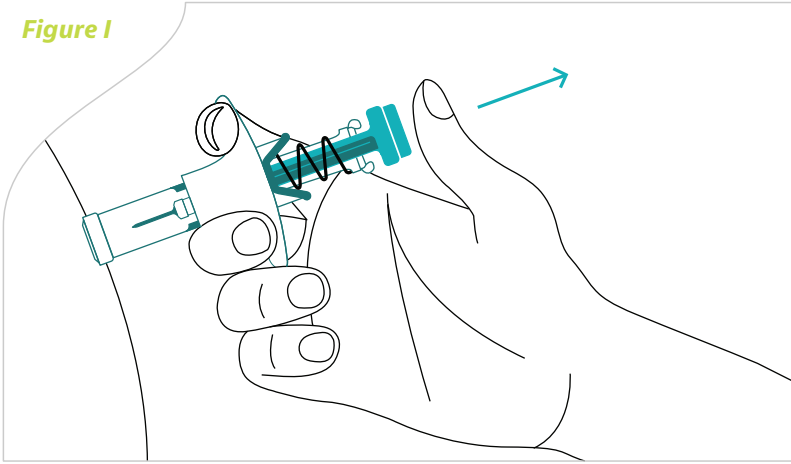
Figure H



> STEP 3: INJECT BIMZELX

3d: Lift your thumb off the plunger head (see Figure I). The needle will automatically move back in and lock in place.

Figure I

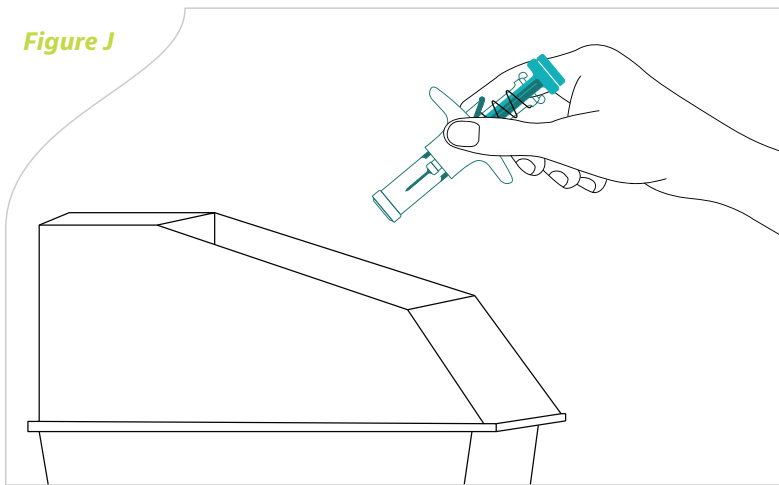


- Press a dry cotton ball over the injection site for a few seconds. Do not rub the injection site. You may see slight bleeding or a drop of liquid. This is normal. You may cover the injection site with a small adhesive **plaster**, if needed.

> STEP 4: DISPOSING OF YOUR INJECTION

Put the used pre-filled syringe in a sharps disposal container straight away after use (see Figure J).

Figure J



For the second injection of your prescribed dose, use a new BIMZELX pre-filled syringe and repeat steps 2 to 4.

Make sure to select a new injection site for your second injection.

 **Bimzelx**[®]
(bimekizumab)

**Remember that our support services staff is available
throughout your experience with BIMZELX®.**

Visit **[UCBCares Level 2]** anytime or call UCBCares® at **XXXX-XXXX**
between the hours of **XXXX-XXXX**, Monday-Friday.

 **Bimzelx**®
(bimekizumab)

These materials are only for patients prescribed BIMZELX.



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Group of Companies.

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GL-N-BK-PSO-2200136
Date of preparation: January 2023