

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **BIMZELX**[®]

bimekizumab injection

Read this carefully before you start taking **Bimzelx (bim zel'ex)** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Bimzelx**.

What is Bimzelx used for?

Bimzelx is used to treat adults with:

- moderate to severe plaque psoriasis
- psoriatic arthritis
- axial spondyloarthritis, including ankylosing spondylitis (radiographic axial spondyloarthritis) and non-radiographic axial spondyloarthritis

Psoriasis is an inflammatory disease of the skin which causes pain, itching and scaling of the skin.

Psoriatic arthritis is a disease that causes inflamed joints, often accompanied by plaque psoriasis.

Axial spondyloarthritis is an inflammatory disease primarily affecting the spine which causes inflammation of the spinal joints. If the condition is not visible using X-rays, it is referred to as “non-radiographic axial spondyloarthritis”; if it occurs in patients with visible signs on X-rays, it is referred to as “ankylosing spondylitis” or “radiographic axial spondyloarthritis”.

How does Bimzelx work?

Bimzelx is a monoclonal antibody belonging to a group of medicines called interleukin (IL) inhibitors. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body. This medicine works by reducing the activity of two proteins called IL-17A and IL-17F, which are present at increased levels in diseases such as plaque psoriasis, psoriatic arthritis and axial spondyloarthritis.

What are the ingredients in Bimzelx?

Medicinal ingredients: bimekizumab

Non-medicinal ingredients: acetic acid, glycine, polysorbate 80, sodium acetate trihydrate and water for injection

No components of Bimzelx are made with natural rubber latex.

Bimzelx comes in the following dosage forms:

Pre-filled syringe 160 mg/mL

Autoinjector 160 mg/mL

Do not use Bimzelx if:

- you are allergic to bimekizumab or to any of the ingredients in this medicine. See **What are the ingredients in Bimzelx?**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Bimzelx. Talk about any health conditions or problems you may have, including if you:

- have an infection that does not go away or that keeps coming back.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with Bimzelx.
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before using this medicine. This is because it is not known if Bimzelx can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Bimzelx and for at least 4 months after the last Bimzelx dose. Talk to your healthcare professional about your contraception options.
- are breastfeeding or plan to breastfeed. It is not known if Bimzelx passes into your breast milk.

Other warnings you should know about:

Bimzelx is not approved for children and adolescents under 18 years of age because it has not been studied in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Bimzelx:

Use Bimzelx exactly as prescribed by your healthcare professional. Check with your healthcare professional if you are not sure. Your healthcare provider should show you or a caregiver how to prepare and inject Bimzelx for the first time. Do not inject yourself or someone else until you have been shown how to inject Bimzelx the right way.

Read '**Instructions for use**' at the end of this leaflet before injecting Bimzelx yourself.

Usual dose:***Plaque psoriasis:***

The usual dose is 320 mg given as two 160 mg injections every 4 weeks for the first 16 weeks, and then every 8 weeks. If you weigh more than 120 kg, your healthcare professional may decide to continue your injections every 4 weeks from week 16.

Psoriatic arthritis:

The recommended dose is 160 mg given as one injection every 4 weeks.

If you have psoriatic arthritis and moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis. After Week 16, your healthcare professional may change your dose to 160 mg every 4 weeks, depending on your joint symptoms.

Axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis):

The usual dose is 160 mg given as one injection every 4 weeks.

Overdose:

If you have taken more Bimzelx than you should or you have taken a dose earlier than prescribed, talk to your healthcare professional.

If you think you, or a person you are caring for, have taken too much Bimzelx, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your Bimzelx dose, inject a dose as soon as you remember. Then, take your next dose at your regular schedule (i.e. 4 or 8 weeks later). Do not take two doses at the same time to make up for the missed dose. Call your healthcare professional if you are not sure what to do.

What are possible side effects from using Bimzelx?

These are not all the possible side effects you may have when taking Bimzelx. If you experience any side effects not listed here, tell your healthcare professional.

Very common: may affect more than 1 in 10 people

- upper respiratory tract infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people

- fungal infections of the mouth (thrush), throat, or vagina
- burning when you urinate or urinating more often than normal (urinary tract infection)
- headache
- injection site reactions (pain, redness or swelling at injection site)

- acne
- small red bumps on your skin
- stomach ache or stomach flu (gastroenteritis)
- diarrhea
- athlete’s foot
- feeling tired or aching
- cold sores
- cough or chest cold
- dry skin
- itchy skin or rash
- toothache
- high blood pressure
- pain in mouth
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Serious infections: fever, sweats, or chills, cough, shortness of breath, blood in phlegm, muscle aches; warm, red, or painful skin or sores on your body different from your psoriasis, weight loss, diarrhea or stomach pain; burning when you urinate or urinating more often than normal		✓	
RARE			
Serious allergic reactions: feeling faint; swelling of your face, eyelids, lips, mouth, tongue, or throat; trouble breathing or throat tightness; or skin rash		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store Bimzelx in the refrigerator at 2 to 8°C (36 to 46°F).
- **Do not** freeze. **Do not** use Bimzelx if it has been frozen.
- Store in the original carton and protect from light.
- If necessary, Bimzelx may be stored at room temperature up to 25°C (77°F), protected from light, for a maximum of up to 25 days, within the expiration date of the product.
 - **Do not** store above 25°C (77°F).
 - Write the date removed from the refrigerator in the space provided on the carton.
 - **Do not** place Bimzelx back in refrigerator after it has been stored at room temperature.
 - Throw away the product if it is not used within 25 days at room temperature.
- **Do not** use Bimzelx after the expiration date shown on the outer carton.
- Keep out of reach and sight of children.

If you want more information about Bimzelx:

- talk to your healthcare professional
- find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <http://www.ucb-canada.ca>, or by calling 1-866-709-8444.

This leaflet was prepared by UCB Canada Inc.

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

Instructions for Use
PrBIMZELX® (bim zel' ex)
bimekizumab injection
Pre-filled syringe

Please read this Instructions for Use before using the Bimzelx pre-filled syringe and each time you get a refill. Each pre-filled syringe is for single-use only.

Important information:

- your healthcare professional should show you or a caregiver how to prepare and inject Bimzelx using the pre-filled syringe for the first time. Do not inject yourself or someone else until you have been shown how to inject Bimzelx the right way. If you still need training, contact your nurse case manager.
- these instructions are for 1 injection only. **Depending on your prescribed dose, you will need to use 1 or 2 injections.** One pre-filled syringe is needed for a 160 mg dose and 2 pre-filled syringes (one after the other) are needed for a 320 mg dose.
- **do not** share or reuse your Bimzelx pre-filled syringe. You may give or get an infection.
- the Bimzelx pre-filled syringe has a needle safety feature that will be activated to cover the needle automatically after the injection is finished. The needle safety feature will help to prevent needle prick injuries to anyone who handles the pre-filled syringe after injection.
- **do not** remove the needle cap until just before you give the injection.

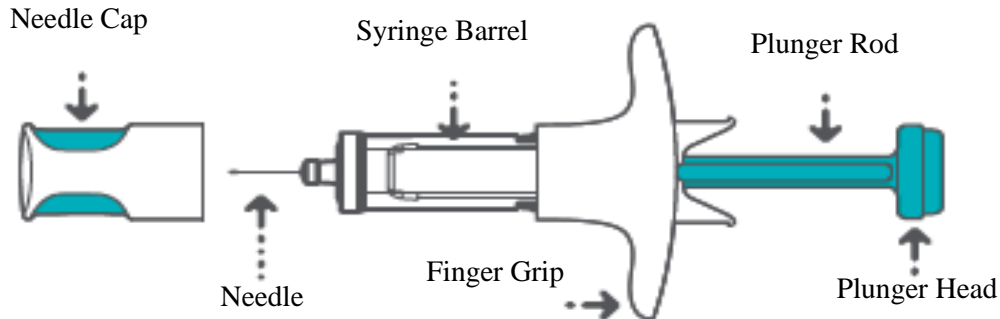
Keep Bimzelx and all medicines out of the reach of children.

How should I store Bimzelx pre-filled syringe?

- Store Bimzelx pre-filled syringe **in the refrigerator** between 2 to 8°C (36 to 46°F). Keep in the original carton to protect from light.
- Do not freeze Bimzelx. Do not use Bimzelx if it has been frozen.

Bimzelx pre-filled syringe parts (see Figure A):

Figure A



For each Bimzelx injection, you will need:

- 1 Bimzelx pre-filled syringe

Not provided in the Bimzelx pre-filled syringe carton:

- 1 alcohol swab
- 1 clean cotton ball
- 1 puncture-resistant sharps container.

Call your nurse case manager if you need help or do not know how to proceed.

Setting up for your Bimzelx injection

Step 1: Take the Bimzelx pre-filled syringe carton out of the refrigerator. Do not use the Bimzelx pre-filled syringe(s) if the carton is damaged or opened. Contact your nurse case manager.

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

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

Step 3: Wash your hands well with soap and water and dry with a clean towel.

Step 4: Gather the supplies for your injection.

Step 5: Inspect the Bimzelx pre-filled syringe (**see Figure B**):

- **Make sure the name Bimzelx appears on the label.**
 - Check the expiry date printed on the label.


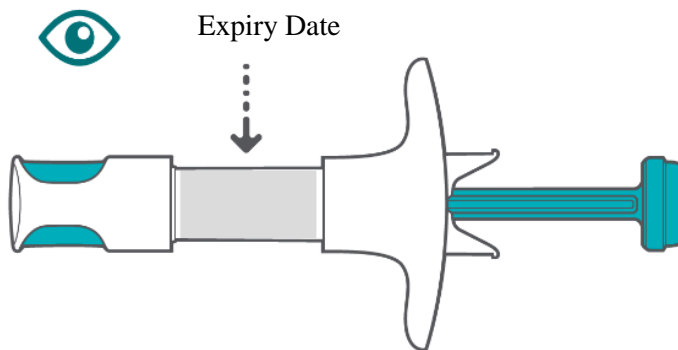
-  Check the medicine through the viewing window. The medicine inside should be clear to slightly opalescent and free of particles. Its colour may vary from colourless to pale brownish-yellow. You may see air bubbles in the liquid. This is normal. Do not try to remove the air bubble.
- **Do not use the Bimzelx pre-filled syringe, and contact your nurse case manager if:**
 - the expiry date printed on the label has passed.
 - the medicine is cloudy, discolored, or has particles.
 - it looks damaged or has been dropped.

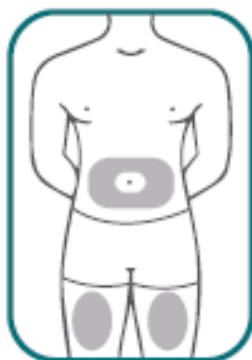
Figure B



Step 6: Choose your injection site

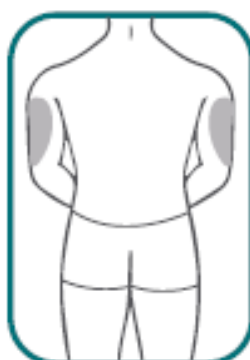
- **The sites you may choose for your injection are:**
 - your stomach area (abdomen) or in your thigh (see **Figure C**).
 - the back of your arm (see **Figure D**). A healthcare provider or caregiver is required to inject in the back of your arm.

Figure C



Abdomen or thigh

Figure D



Back of arm

- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard or areas with scars or stretch marks or within 2 inches of the belly button (navel).
- If a second injection is needed for your prescribed dose (320 mg), choose a different site for your second injection. You should try to rotate between the areas shown in the diagram above. If you cannot use a different site for each injection, make sure each injection is at least one inch (two fingers) apart. **Do not** use the same place to inject twice in a row.

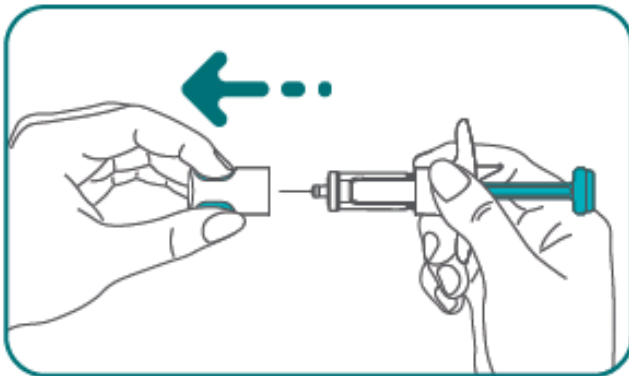
Step 7: Prepare your skin.

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

Step 8: Remove the Bimzelx pre-filled syringe needle cap.

- Hold the Bimzelx 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, contact your nurse case manager.
 - **Do not** put the needle cap back on.

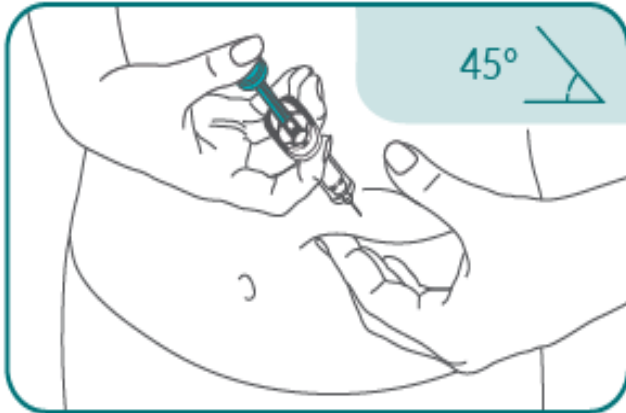
Figure E



Step 9: 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.

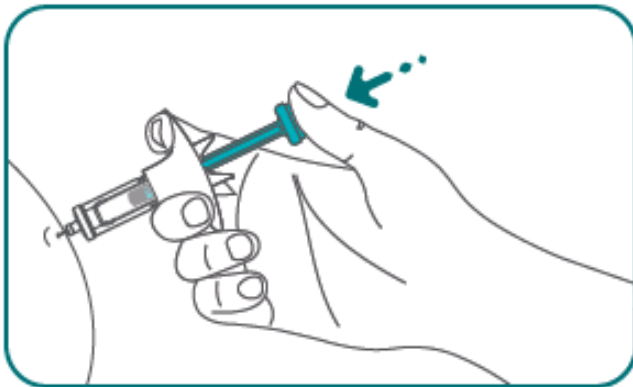
- Push the needle all the way in to make sure that you inject your full dose. Then gently let go of your skin. Make sure the syringe stays close to the skin so that the needle does not come out (see **Figure F**).

Figure F



Step 10: Firmly push the plunger head all the way down until all the medicine is injected. (see **Figure G**).

Figure G



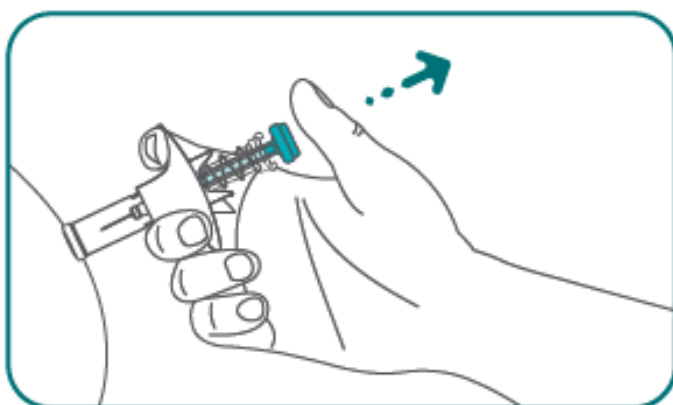
- All the medicine is injected when you cannot push the plunger head any further (see **Figure H**).

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.

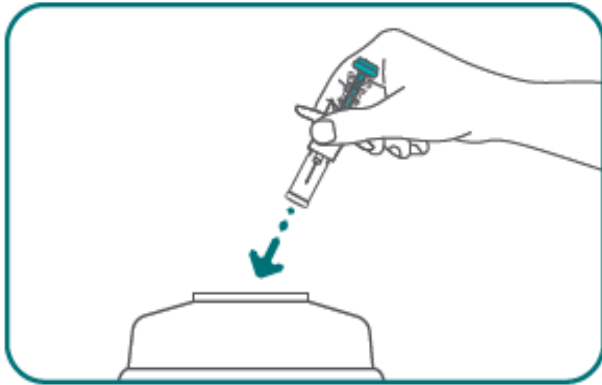
Figure I



- Press a dry 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.
- **If you need to give a second injection for your prescribed dose, use a new Bimzelx pre-filled syringe and repeat Steps 1 to 12.**
- Make sure to select a new injection site for your second injection. **Do not** use the same site that you used for your first injection.

Step 12: Dispose of (throw away) the used Bimzelx pre-filled syringe (see Figure J).

Figure J



- Put the used Bimzelx pre-filled syringe in sharps container right away after use.
- When your sharps container is almost full, contact your nurse case manager for disposal information.
- **Do not** recycle your used sharps container.

Instructions for Use
PrBIMZELX® (bim zel' ex)
bimekizumab injection
Autoinjector

Please read this Instructions for Use before using Bimzelx autoinjector and each time you get a refill. There may be new information. Each autoinjector is for single-use only.

Important information:

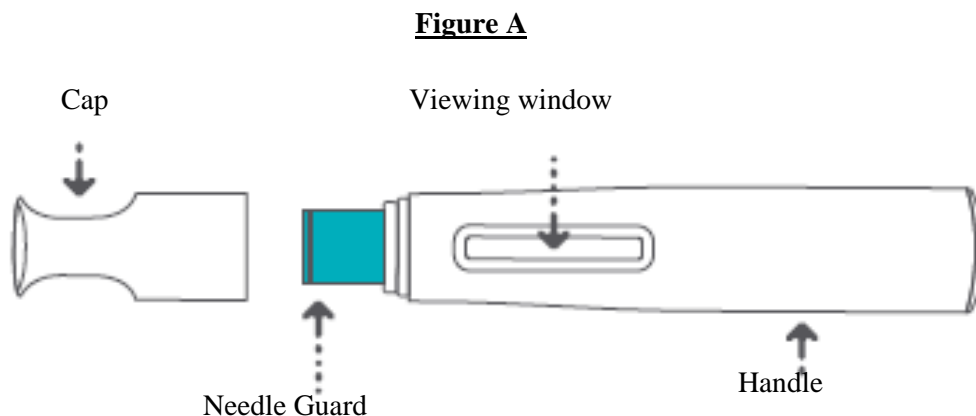
- your healthcare professional should show you or a caregiver how to prepare and inject Bimzelx using the autoinjector for the first time. Do not inject yourself or someone else until you have been shown how to inject Bimzelx the right way. If you still need training, contact your nurse case manager.
- these instructions are for 1 injection only. **Depending on your prescribed dose, you will need to use 1 or 2 injections.** One autoinjector is needed for a 160 mg dose and 2 autoinjectors (one after the other) are needed for a 320 mg dose.
- **do not** share or reuse your Bimzelx autoinjector. You may give or get an infection.
- if you have vision or hearing problems, **do not** use Bimzelx autoinjector without help from a caregiver.

Keep Bimzelx and all medicines out of the reach of children.

How should I store Bimzelx autoinjector?

- Store Bimzelx autoinjector **in the refrigerator** between 2 to 8°C (36 to 46°F). Keep in the original carton to protect from light.
- Do not freeze Bimzelx. Do not use Bimzelx if it has been frozen.

Bimzelx autoinjector parts (see Figure A):



For each Bimzelx injection, you will need:

- 1 Bimzelx autoinjector

Not provided in the Bimzelx autoinjector carton:

- 1 alcohol swab
- 1 clean cotton ball
- 1 puncture-resistant sharps disposal container.

Call your nurse case manager if you need help or do not know how to proceed.

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 is damaged or opened. Contact your nurse case manager.

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

Step 4: Gather the supplies needed for your injection.

Step 5: Inspect the Bimzelx autoinjector (see Figure B):


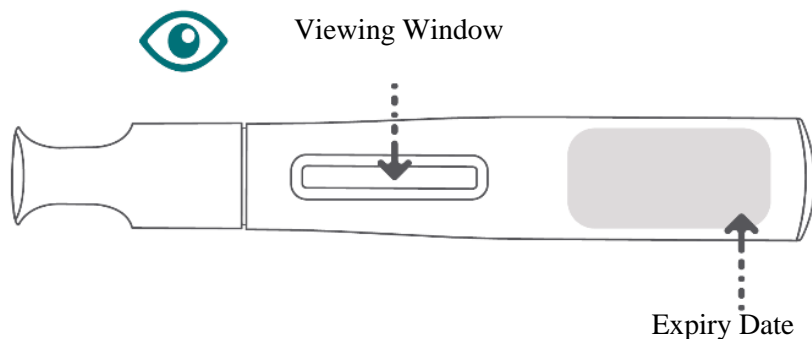
- **Make sure the name Bimzelx appears on the label.**
 - Check the expiry date printed on the label.
 -  Check the medicine through the viewing window. The medicine inside should be clear to slightly opalescent and free of particles. Its colour may vary from colourless to pale brownish-yellow. You may see air bubbles in the liquid. This is normal. Do not try to remove the air bubble.
- **Do not use the Bimzelx autoinjector**, and contact your nurse case manager if:
 - the expiry date printed on the label has passed
 - the medicine is cloudy, discolored, or has particles.
 - it looks damaged or has been dropped.

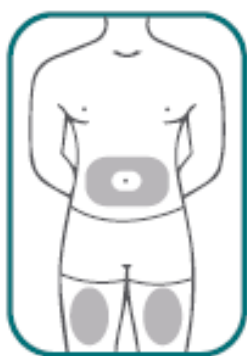
Figure B



Step 6: Choose your injection site.

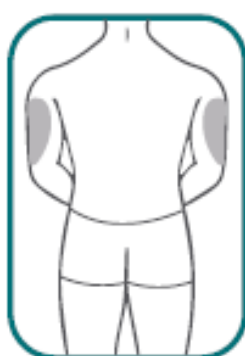
- **The sites you may choose for your injection are:**
 - your stomach area (abdomen) or your thigh (**see Figure C**).
 - the back of your arm (**see Figure D**). A healthcare provider or caregiver is required to inject in the back of your arm.

Figure C



Abdomen or thigh

Figure D



Back of arm

- **Do not** inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks, or within 2 inches of the belly button (navel).
- If a second injection is needed for your prescribed dose (320 mg), choose a different site for your second injection. You should try to rotate between the areas shown in the diagram above. If you cannot use a different site for each injection, make sure each injection is at least one inch (two fingers) apart. **Do not** use the same place to inject twice in a row.

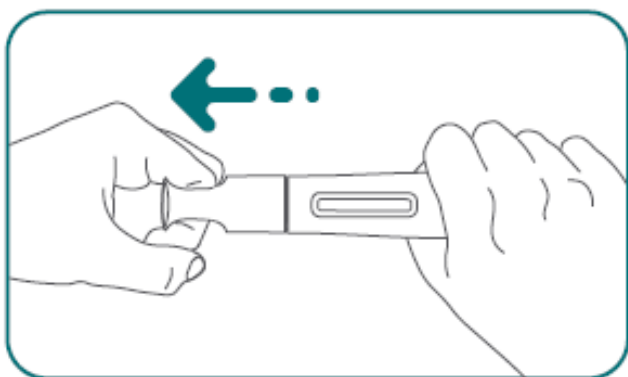
Step 7: Prepare your skin.

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

Step 8: Remove the Bimzelx autoinjector cap.

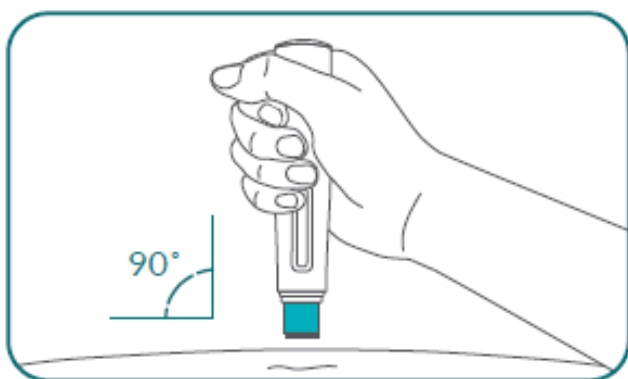
- Hold the autoinjector firmly with one hand around the handle. Pull the cap straight off the autoinjector with the other hand (see **Figure E**). Although you cannot see the needle tip, it is now uncovered.
 - **Do not** touch the needle guard or put the cap back on as it could activate the autoinjector and you can prick yourself.
 - **Do not** twist the handle when pulling the cap off.

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 (you may need to pull the skin tight for the autoinjector to rest 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 first “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 second “click” within 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).

Figure G

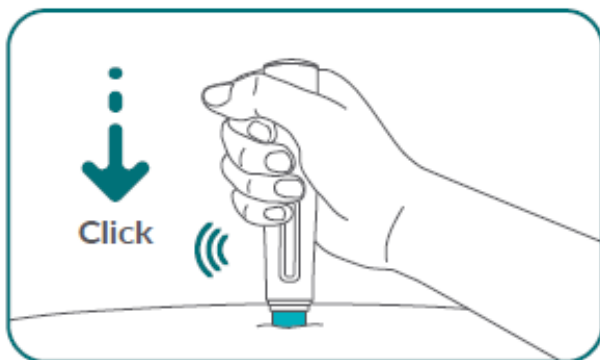
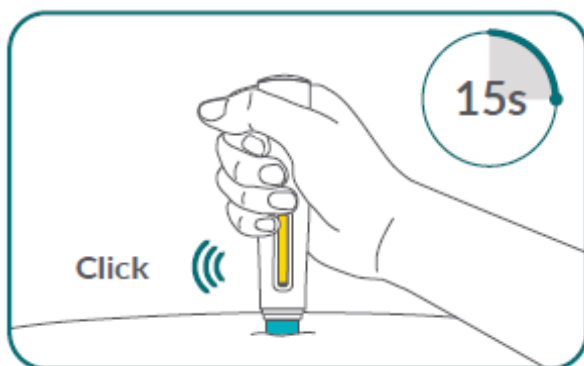


Figure H



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 dry cotton ball over the injection site for a few seconds. **Do not** rub the injection site. You may see slight bleeding or drop of liquid. This is normal. You may cover the injection site with a small adhesive bandage, if needed.
- **If you need to give a second injection for your prescribed dose, use a new Bimzelx autoinjector, and repeat Steps 1 to 12.**
- Make sure you select a new injection site for your second injection. **Do not** use the same site that you used for your first injection.

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

- Put the used Bimzelx autoinjector in sharps container right away after use.

Figure I



- When your sharps container is almost full, contact your nurse case manager for disposal information.
- Do not recycle your used sharps disposal container.