

For Persons Undergoing Treatment with Bimzelx®

Risk Management Plan
(RMP)

This material was prepared based
on the Risk Management Plan.

Guide Booklet for Self-Injection



Inspired by patients.
Driven by science.

For Patients Starting Self-Injection

Bimzelx® is designed so that the patients can perform self-injection easily, taking into account the patients' lifestyle and physical condition.

Bimzelx® is a medicine for subcutaneous injection and available in two dosage forms, "autoinjector" and "syringe." This guide booklet explains the procedures and key points for self-injecting Bimzelx® safely and correctly.

If you have any questions after reading this guide booklet, please ask your doctor, nurse, or pharmacist.

Important Precautions

For safe and correct self-injection, the person who actually performs self-injection needs to receive a full explanation from his or her doctor and then practice the self-injection technique under the guidance of his or her doctor, nurse, or pharmacist. When the doctor determines that the self-injection technique has been acquired, self-injection is allowed. Always follow the precautions during the treatment with Bimzelx®.

Table of Contents

Dosage Forms / Steps to Start Self-Injection	5
Dosing Regimen	6
Points to Note for Correct and Safe Self-Injection . .	10
Adverse Reactions	11
Storage Condition	12
Injection Sites	13
Preparation for Injection	14

Autoinjector

Features of Bimzelx® Autoinjector 160 mg / 320 mg for Subcutaneous Injection	16
How to Remove the Cap	17
How to Inject Bimzelx® [For injection in the Abdomen]	18
How to Inject Bimzelx® [For injection in the Thighs]	21
For Injection by Persons Other Than the Patient	23
Cleanup	25

Syringe

Features of Bimzelx® Syringe 160 mg for Subcutaneous Injection	26
How to Remove the Cap	27
How to Inject Bimzelx® [For injection in the Abdomen]	28
How to Inject Bimzelx® [For injection in the Thighs]	30
For Injection by Persons Other Than the Patient	32
Cleanup	34
How to Reduce Injection Pain	35

Q&As about Self-Injection

Q & As	36
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Dosage Forms and Steps to Start Self-Injection

● Dosage forms

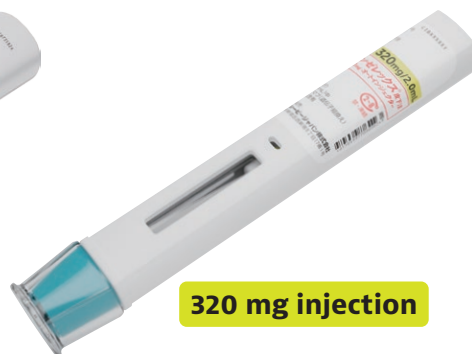
Available in two dosage forms, autoinjector and syringe.

The autoinjectors are available in 160 mg injection and 320 mg injection.

Autoinjector



160 mg injection



320 mg injection

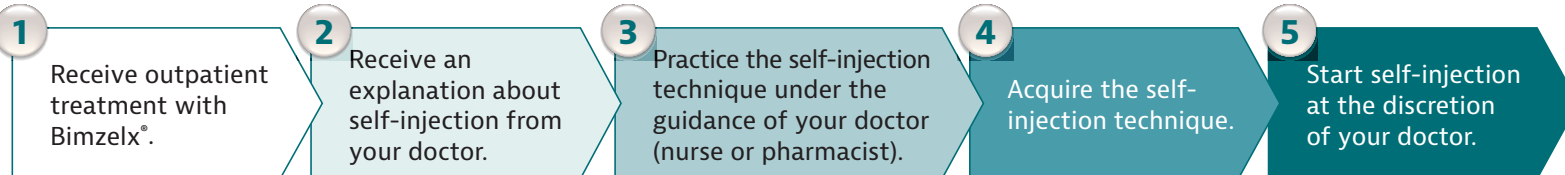
Syringe



160 mg injection

● Steps to start self-injection

Follow the steps below to start self-injection.



- The duration and frequency of practice vary from patient to patient.
- During this period, you perform the self-injection of Bimzelx® with your doctor, nurse, or pharmacist in an outpatient setting.
- Observe the decision by a physician regarding the availability of self-injection. For self-injection, it is necessary to receive training by healthcare professionals to ensure adequate understanding and a safe procedure.

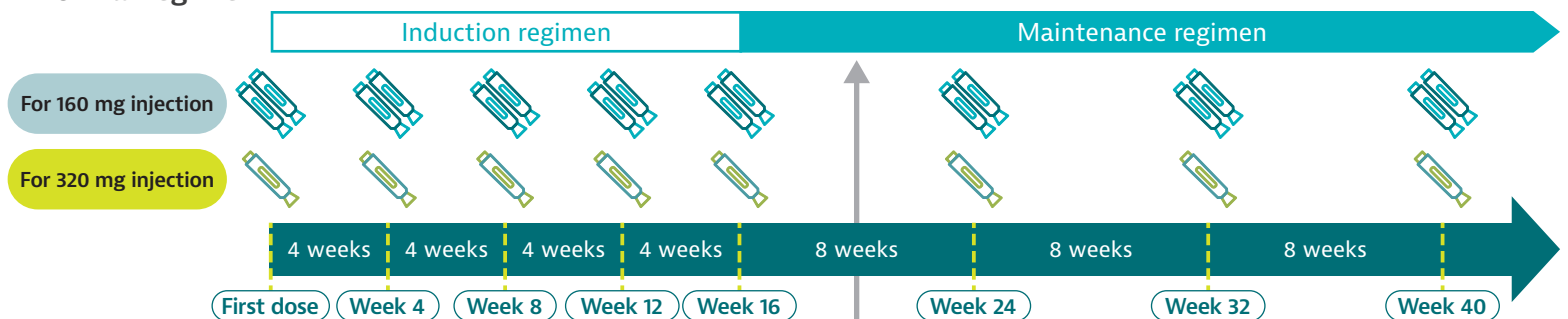
Dosing Regimen

< For Psoriasis Vulgaris, Pustular Psoriasis, and Psoriatic Erythroderma >

- Normally, 320 mg per dose (two 160 mg injections or one 320 mg injection) is subcutaneously administered every 4 weeks from the first dose through week 16, and every 8 weeks thereafter.
- Self-injection is an option only for administration every 4 weeks.

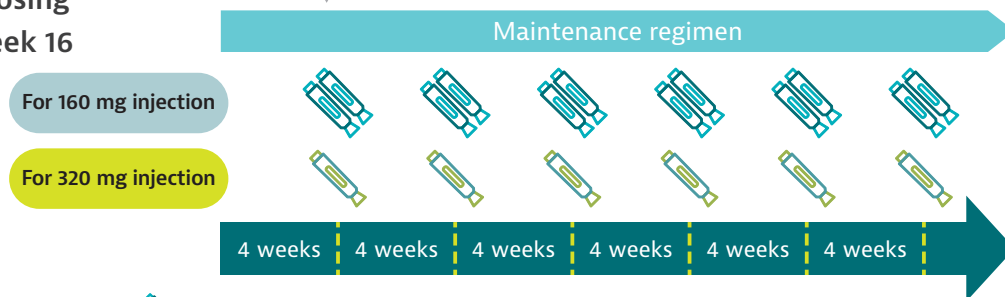
* Subcutaneous injection every 4 weeks may be continued after week 16 depending on the condition of the patient.

- Normal regimen



The dosing interval is determined through consultation with the physician, considering the background and condition of the patient.

- In the case that the regimen with dosing every 4 weeks is continued after week 16

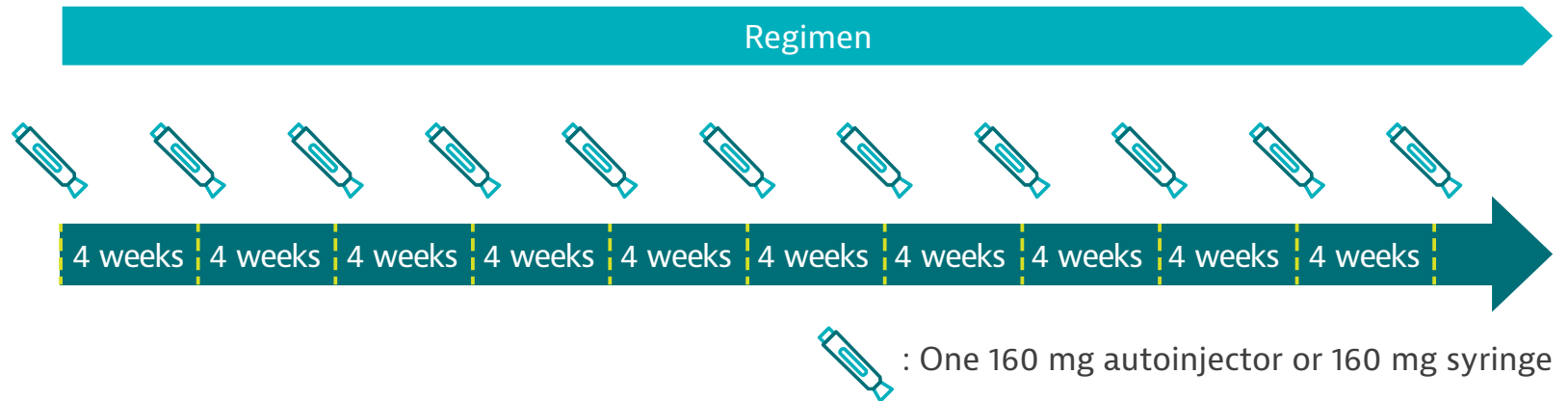


: Two 160 mg autoinjectors or 160 mg syringes : One 320 mg autoinjector

Dosing Regimen

< For Psoriatic Arthritis >

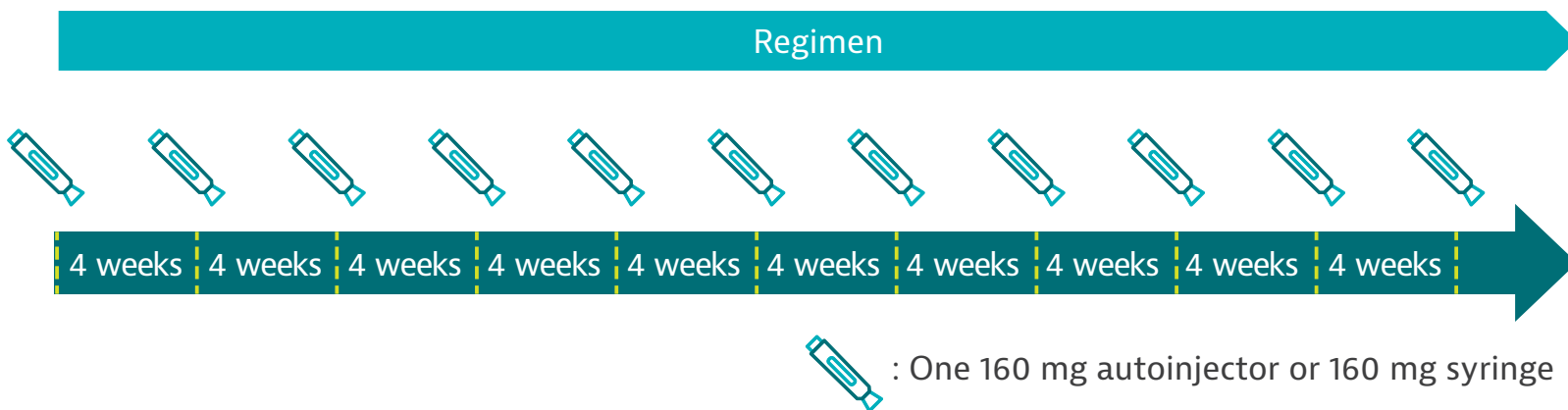
- Normally, 160 mg per dose (one 160 mg injection) is subcutaneously injected every 4 weeks.



Dosing Regimen

< For Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis >

- Normally, 160 mg per dose (one 160 mg injection) is subcutaneously injected every 4 weeks.



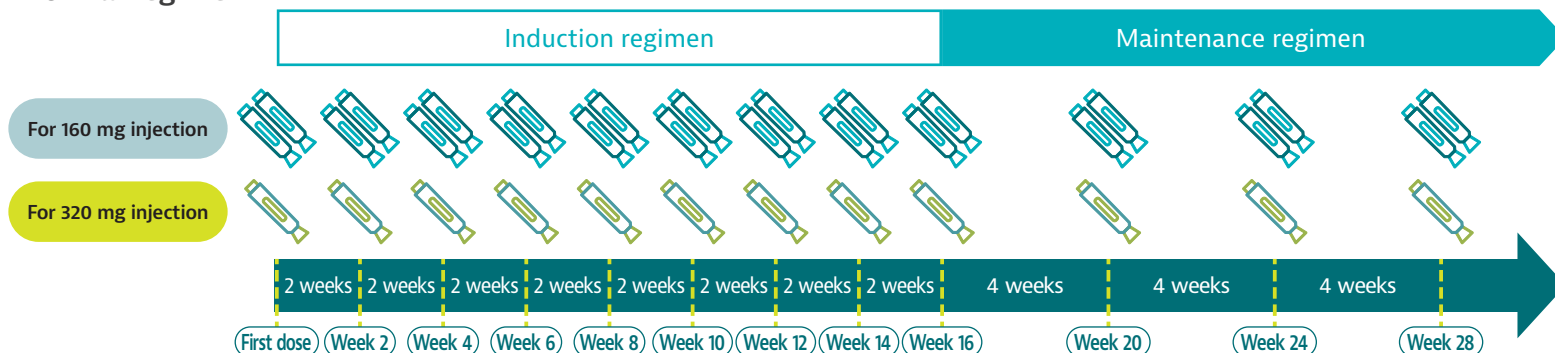
Dosing Regimen

< For Hidradenitis Suppurativa >

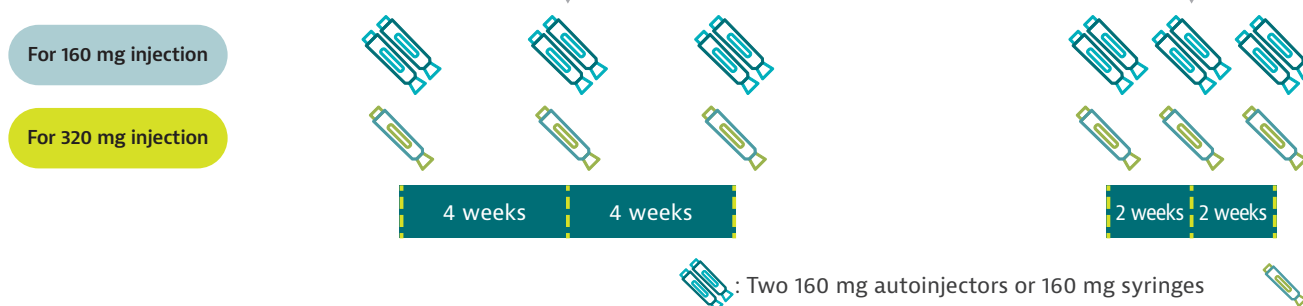
- Normally, 320 mg per dose (two 160 mg injections or one 320 mg injection) is subcutaneously administered every 2 weeks from the first dose through week 16, and every 4 weeks thereafter.



* The dosing interval may be adjusted to every 2 or 4 weeks as appropriate, depending on the condition of the patient.

- Normal regimen



The dosing interval may be adjusted to every 2 or 4 weeks as appropriate, depending on the condition of the patient.



 : Two 160 mg autoinjectors or 160 mg syringes  : One 320 mg autoinjector

Points to Note for Correct and Safe Self-Injection

- For safe and correct self-injection, the person who actually performs self-injection needs to receive a full explanation from his or her doctor and then practice the self-injection technique under the guidance of his or her doctor, nurse, or pharmacist.
- Your doctor decides whether you have acquired the self-injection technique and are ready to start self-injection at home.
- Even after you start self-injection, you may be switched to outpatient injection therapy in the following cases.

When the patient wants to switch to outpatient injection therapy.

When your doctor determines that outpatient injection therapy is desirable.

- If your doctor determines that you need to practice self-injection again because, for example, you cannot perform self-injection properly, you may be switched to outpatient injection therapy and provided with the training again under the guidance of your doctor, nurse, or pharmacist.
- If you have any difficulty or questions about self-injection, always consult your doctor, nurse, or pharmacist.

Adverse Reactions

Most common adverse reactions with Bimzelx® reported in Japan and overseas include the following.

Oral candidiasis

Due to compromised immune function and a deteriorated oral condition, Candida, a type of resident fungus, abnormally increases, causing oral or tongue pain, white tongue fur adhesion, taste disorder, and other symptoms.



Upper respiratory tract infection / nasopharyngitis

Infection is usually caused by viral adhesion to the nasopharynx through the pharyngeal mucosa, causing runny nose, sneezing, nasal congestion, sore throat, and other symptoms.



Hypersensitive reaction

In rare cases, anaphylaxis (with a drop in blood pressure, difficulty breathing, etc.), atopic dermatitis, and other allergic reactions may result from treatment.



Immediately notify your doctor, nurse, or pharmacist if you have any of the following conditions.

- Oral pain, tongue pain, or taste disorder
- Persistent cold-like conditions, such as fever, coughing, runny nose, sore throat, headache, and chills
- Unusual rash (such as nettle rash) and itching of the skin
- Shortness of breath
- Cold sweats or palpitations
- Sluggishness
- Abdominal pain, diarrhea, mucous or bloody feces
- Loss of weight or appetite
- Anal discomfort, pain, or abscess

Storage Condition

Do not use if the expiration date has passed.



Store the medicine received at a medical institution in the refrigerator (2-8°C), avoiding freezing, keeping it in the outer box so as not to be affected by light, until the time of injection.

Do not put it in chilled or vegetable compartments or near the cold air vent because the medicine may freeze. Tell your family members that the medicine (syringe) is in the refrigerator and it should not be taken out.



Avoid storing the medicine in a freezer compartment or a place exposed to direct sunlight or high temperature/humidity. It may cause degradation of the medicine.



Keep the medicine out of reach of children.

*Tell your family members that the box contains a medicine (syringe).

Handle it with care to ensure that it is not used or taken out by children accidentally.



Use a cooler bag when going out or returning home from the hospital with the medicine, and store in a refrigerator at home.



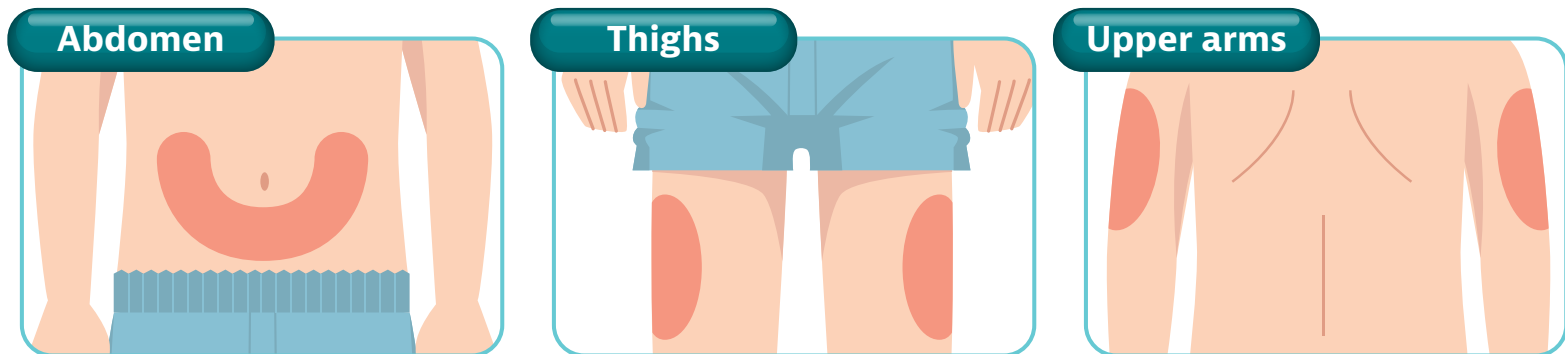
*If the medicine is removed from the refrigerator, keeping it in the outer box at not more than 25°C so as not to be affected by light, use it within 30 days, not beyond the expiration date, and do not return it to the refrigerator again. It is recommended to record on the outer box the date when the medicine is removed from the refrigerator.

Injection Sites


*Check with your doctor, nurse, or pharmacist about the injection site before proceeding.

- The injection sites for the autoinjector and syringe are the same.
- If injection is performed by the patient, inject in the abdomen or thigh.
- If persons other than the patient perform the injection, the upper arm is also an option.

***Even when the injection is performed by persons other than the patient, they must receive guidance on the injection method.**



Avoid the area around the navel (about 5 cm).

-  When two syringes are administered in one dose, the sites of the two injections should be at least 3 cm apart.
- Inject at a site different from the previous injection.
- Avoid a 5 cm area around the navel for injection in the abdomen.
- Avoid areas with dermal symptoms (such as redness, rash, peeling scales, bumps, and hardness), injury, or pain.
- If you are allergic to alcohol swabs, notify your doctor, nurse, or pharmacist.

Preparation for Injection (1)

1 Take the box containing the medicine out of the refrigerator, place it on a flat surface as it is for at least 30 minutes to return it to room temperature.

- When returning it to room temperature, do not use a microwave or warm water.
- Do not shake the product.

2 Secure a bright and flat place and keep the surface of the table clean.

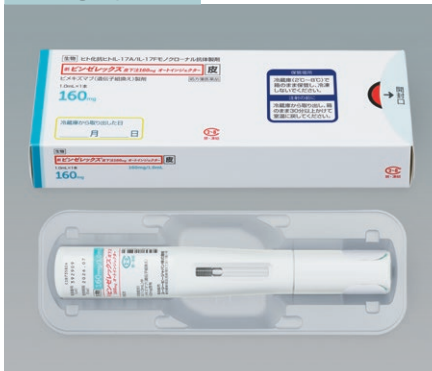
3 Wash hands thoroughly with soap.

4 Take the autoinjector or syringe out of the box.

- Do not remove the cap until just before the injection.
- Do not recap it.

Autoinjector

160 mg injection



320 mg injection



Syringe

160 mg injection



Hold the syringe
(at the label part)
and take it out.

* As for the autoinjector and the syringe, one product is contained in one box, and both are for single-use. The orientation of the box and autoinjector or syringe in the photo matches the actual packaging.

Preparation for Injection (2)

5 Visually inspect the contents before injection.

- Do not use if the injection solution is discolored (originally, the injection solution is colorless, clear light brown-yellow, or slightly turbid light brown-yellow).
- Do not use if obvious particulate matters or turbidity are observed in the solution.
- Do not use if the autoinjector or syringe has cracks or other damage.
- Do not use if dropped on a hard surface.
- Do not remove the cap until preparation for injection of this medicine is completed.



- If any abnormality is found, always notify your doctor, nurse, or pharmacist before you inject it.
- If you feel unwell on the day of injection, consult your doctor before injection.

Features of Bimzelx[®] Autoinjector

160 mg / 320 mg for Subcutaneous Injection

160 mg injection

Window for checking the drug solution

At the completion of the injection of the drug solution, the window color turns yellow.

Buttonless design

As manipulation using a button is not needed, injection can be performed easily.

Producing a confirmation sound twice

The autoinjector reminds you of the start and completion of injection with a sound.

Uncapped tip

Needle guard hiding the needle tip

The needle guard that covers the needle tip gives a sense of security even to patients who are uncomfortable with injections.



Cap

Needle guard

320 mg injection

Window for checking the drug solution

Just before the completion of the injection of the drug solution, the window color turns yellow.

Buttonless design

As manipulation using a button is not needed, injection can be performed easily.

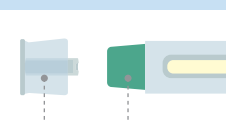
Producing a confirmation sound twice

The autoinjector reminds you of the start and completion of injection with a sound.

Uncapped tip

Needle guard hiding the needle tip

The needle guard that covers the needle tip gives a sense of security even to patients who are uncomfortable with injections.



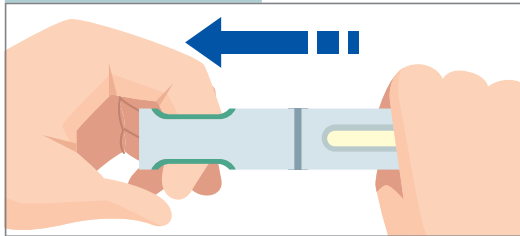
Cap

Needle guard

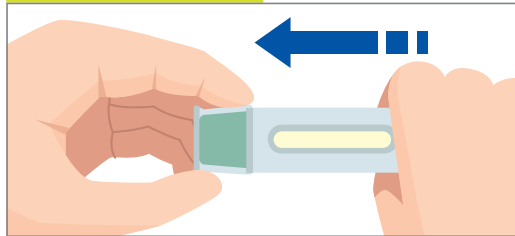
How to Remove the Cap

Grip the handle firmly with one hand and remove the cap with the other hand.

160 mg injection



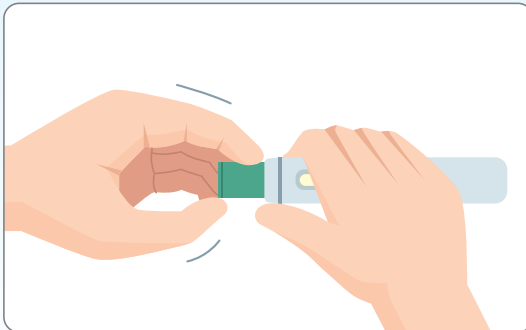
320 mg injection



[Reference]
Another method to remove the cap

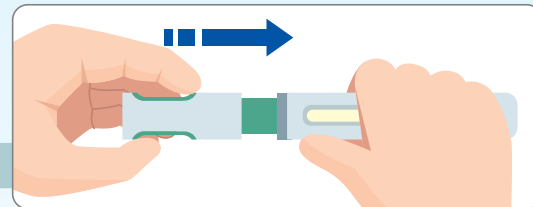


Precautions when removing the cap

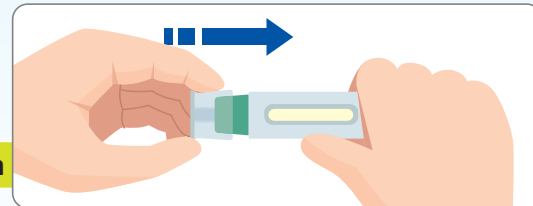


Do not touch the tip (needle guard).

160 mg injection



320 mg injection



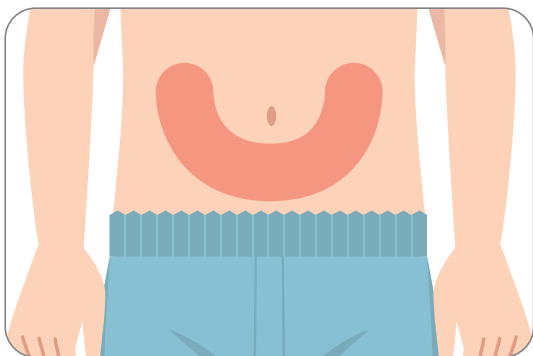
Do not put back the cap once removed.

How to Inject Bimzelx[®]

[For Injection in the Abdomen](1)

● Injection site

Sit on a chair, etc. in a relaxed position.



Avoid the area around the navel (about 5 cm)

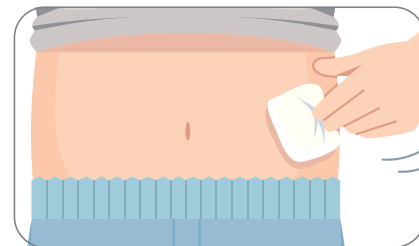
● How to inject

- Inject at a site different from the previous injection.
- When two autoinjectors are administered in one dose, the sites of the two injections should be at least 3 cm apart.

1 Disinfect the injection site (skin) with an alcohol pad.

Wipe in a circular motion from the center outward, and dry well.

Do not touch the disinfected area until injection.



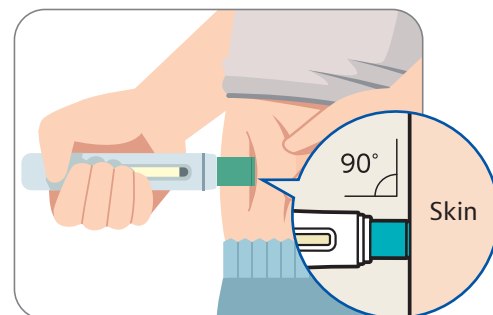
2 Remove the cap safely and cleanly.

Grip the handle of the autoinjector firmly with one hand and remove the cap with the other hand.

Once the cap is removed, inject as soon as possible.

3 Place the autoinjector on the injection site.

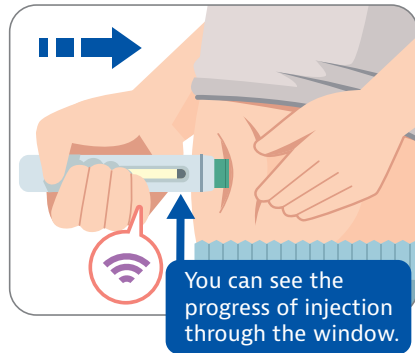
Gently pinch the skin at the injection site with one hand. Grip the handle with the other hand while making the window for checking the drug solution visible and press the tip (needle guard) at a 90-degree angle to the skin.



How to Inject Bimzelx[®]

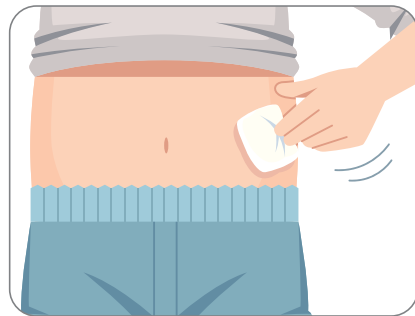
[For Injection in the Abdomen] (2)

4 Press the autoinjector against the injection site.



Press the autoinjector directly onto the injection site, and you will hear the confirmation sound, and the injection of the drug solution will start.

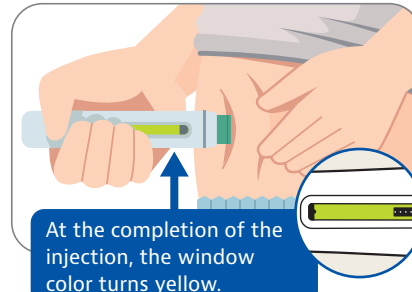
6 Gently press and confirm that bleeding has stopped.



Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

Do not rub the injection site.

5 Wait.



160 mg Injection

Completion of injection.

320 mg Injection

While further continuing to press the autoinjector against your skin, slowly count 5 seconds, and the injection is complete.

160 mg Injection

When the injection is completed within 15 seconds, you will hear the second confirmation sound. When the window for checking the drug solution turns yellow, the injection is complete.

320 mg Injection

Within 15 seconds from the start of injection, you will hear the second confirmation sound and see the color of the window for checking the drug solution turns yellow. While further continuing to press the autoinjector against the injection site, slowly count 5 seconds, and the injection is complete.

After confirming the completion of injection, pull the autoinjector straight out of the injection site. The needle guard will automatically cover the needle to prevent accidental needle sticks.

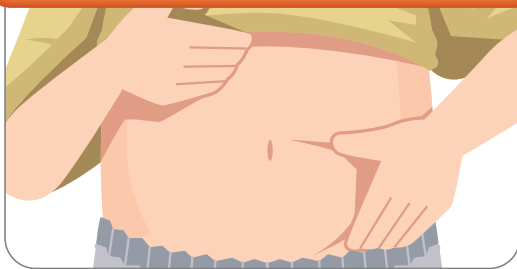
Do not detach the autoinjector from your body until the injection is complete.

How to Inject Bimzelx[®]

[For Injection in the Abdomen] (3)

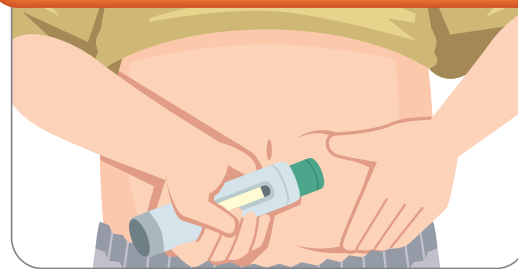
- Have your doctor or nurse check your skin condition. Injection will be performed by stretching or pinching the skin according to the skin condition of each patient.

Injection by stretching the skin



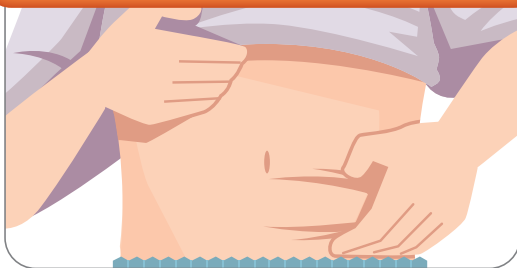
If the skin of the injection site is sagged, perform the injection while stretching it out.

Injection in a standing position



A standing position makes the skin of the abdomen more resilient, which allows for an easier injection.

Injection by pinching the skin



If you have low subcutaneous fat (the width between your fingers is not more than 2 cm when pinching the injection site), perform the injection while pinching the injection site.

Injection with both hands

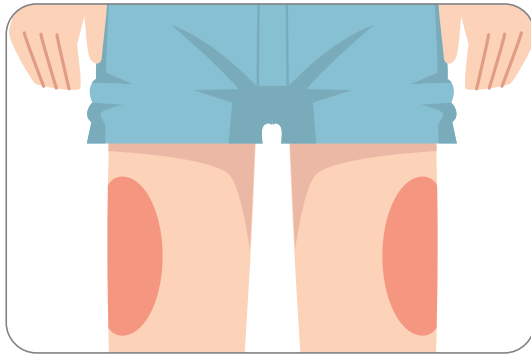


If you have a disorder of joints in the hand or a decline in grip strength, perform the injection with both hands.

How to Inject Bimzelx[®] [For Injection in the Thighs] (1)

● Injection site

Sit on a chair, etc. in a relaxed position.



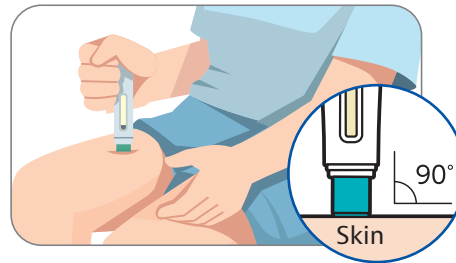
Avoid areas 5 cm above the knee joint and 5 cm below the groin.

● How to inject

1 Disinfect the injection site (skin) with an alcohol swab.

2 Remove the cap safely and cleanly.

3 Place the autoinjector on the injection site at a 90-degree angle to the skin.



- Inject at a site different from the previous injection.
- When two autoinjectors are administered in one dose, the sites of the two injections should be at least 3 cm apart.

How to Inject Bimzelx[®]

[For Injection in the Thighs] (2)

4 Press the autoinjector against the injection site.



If you have low subcutaneous fat (the width between your fingers is not more than 2 cm when pinching the injection site), perform the injection while pinching the injection site.

Press the autoinjector directly onto the injection site, and you will hear the confirmation sound, and the injection of the drug solution will start.

6 Gently press and confirm that bleeding has stopped.



Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

Do not rub the injection site.

5 Wait.



160 mg Injection

When the injection is completed within 15 seconds, you will hear the second confirmation sound. When the window for checking the drug solution turns yellow, the injection is complete.

After confirming the completion of injection, pull the autoinjector straight out of the injection site. The needle guard will automatically cover the needle to prevent accidental needle sticks.

Do not detach the autoinjector from your body until the injection is complete.

320 mg Injection

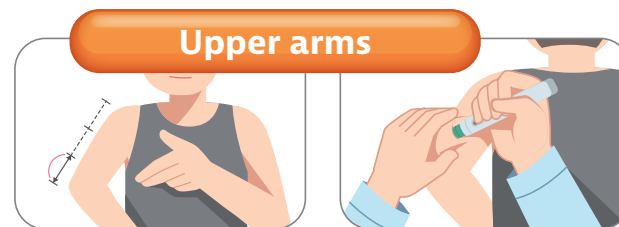
Within 15 seconds from the start of injection, you will hear the second confirmation sound and see the color of the window for checking the drug solution turns yellow. While further continuing to press the autoinjector against the injection site, slowly count 5 seconds, and the injection is complete.

For Injection by Persons Other Than the Patient (1)

● Injection sites / How to inject

Even if the injection is given by any person other than you, be sure to receive guidance on how to inject Bimzelx®.

- 1 Disinfect the injection site (skin) with an alcohol pad.
- 2 Remove the cap safely and cleanly.
- 3 Place the autoinjector on the injection site at a 90-degree angle to the skin.
- 4 Pinch the skin firmly with the hand opposite to that holding the autoinjector.
 - Inject at a site different from the previous injection.
 - When two autoinjectors are administered in one dose, the sites of the two injections should be at least 3 cm apart.

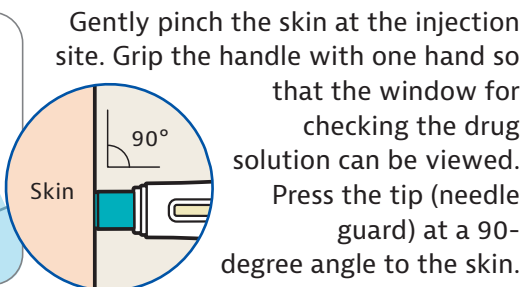


- Have the patient bend the arm at a 90-degree angle and support it with the other hand, or stabilize the arm by putting the hand on the hip.
- When the length from the tip of the shoulder to the tip of the elbow is divided into equal thirds, the position at about the first third from the tip of the elbow is the injection site.
- Inject into the back side of the upper arm.

For Injection by Persons Other Than the Patient (2)

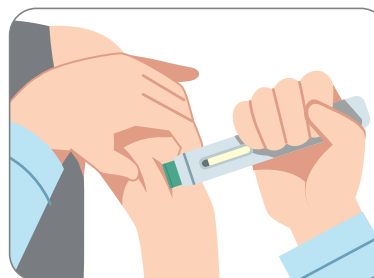
● How to inject Bimzelx® [for injection in the upper arms]

1 Place the autoinjector on the injection site.



Gently pinch the skin at the injection site. Grip the handle with one hand so that the window for checking the drug solution can be viewed. Press the tip (needle guard) at a 90-degree angle to the skin.

2 Press the autoinjector against the injection site.



Press the autoinjector directly onto the injection site, and you will hear the confirmation sound, and the injection of the drug solution will start.

3 Wait.



160 mg Injection

When the injection is completed within 15 seconds, you will hear the second confirmation sound. When the window for checking the drug solution turns yellow, the injection is complete.

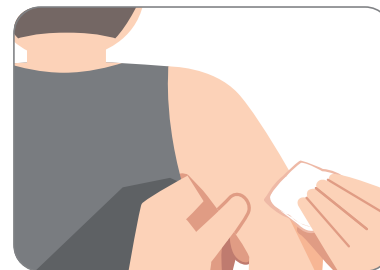
320 mg Injection

Within 15 seconds from the start of injection, you will hear the second confirmation sound and see the color of the window for checking the drug solution turns yellow. While further continuing to press the autoinjector against the injection site, slowly count 5 seconds, and the injection is complete.

After confirming the completion of injection, pull the autoinjector straight out of the injection site. The needle guard will automatically cover the needle to prevent accidental needle sticks.

Do not detach the autoinjector from your body until the injection is complete.

4 Gently press and confirm that bleeding has stopped.



Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

Do not rub the injection site.

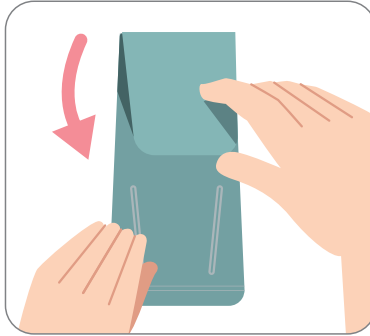
Cleanup

1 Put in the disposal bag.



Open the lid of the disposal bag and put the used autoinjector in the bag.

2 Close the bag.

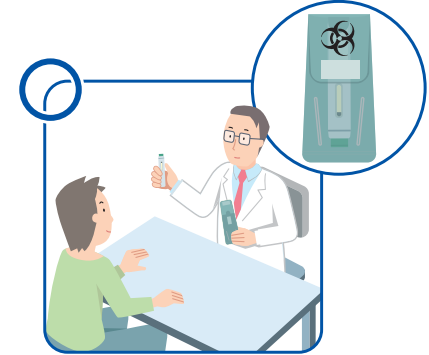


Close the lid of the disposal bag and fasten with the hook-and-loop fastener.

- Do not recap the autoinjector after injection.
- Dispose of alcohol pads and caps as household waste unless otherwise specified.
- Put the used autoinjector in the dedicated disposal bag, keep it in a place out of reach of children, and dispose of it as directed by the medical institution.
- Do not dispose of used autoinjectors as household waste.



Alcohol pads and caps are household waste.



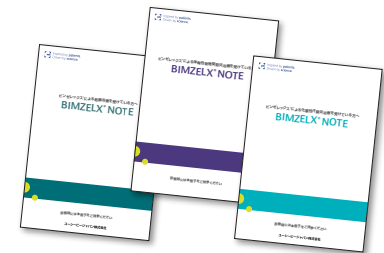
Autoinjectors are medical waste.

Keep records.

Keep records from the day you start injecting Bimzelx®.

Please use the **BIMZELX® NOTE**.

It is useful for early detection of changes in the skin and joint conditions and adverse reactions. Bring your **BIMZELX® NOTE** with you when you visit the medical institution and always show it to your doctor.



BIMZELX® NOTE

Features of Bimzelx[®] Syringe 160 mg for Subcutaneous Injection

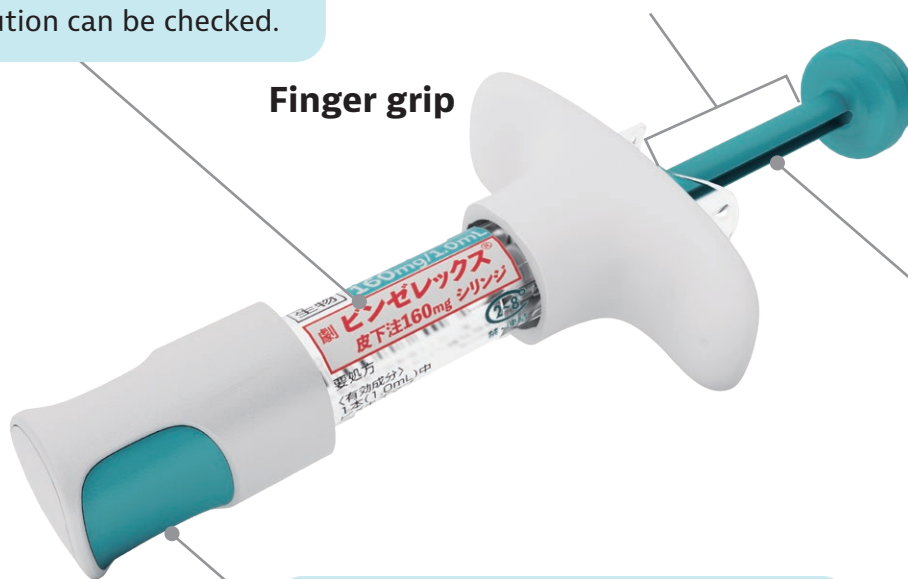
The drug solution is visible from any direction.

The progress of the injection of the drug solution can be checked.

Plunger rod

Finger grip

Head



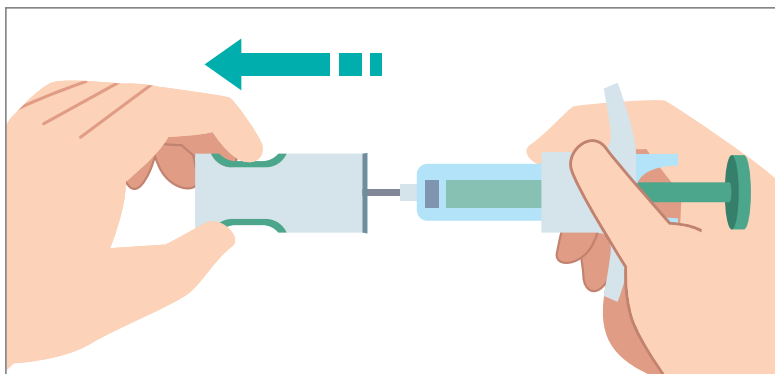
Easy to check the progress of injection.



When pushed fully to the end.

The needle is automatically retracted into the main body.

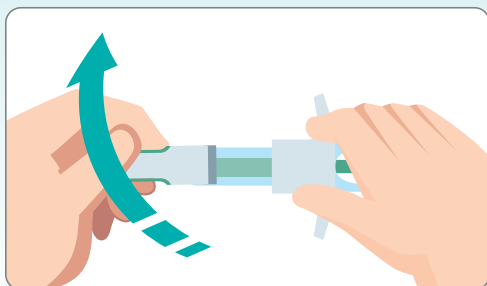
How to Remove the Cap



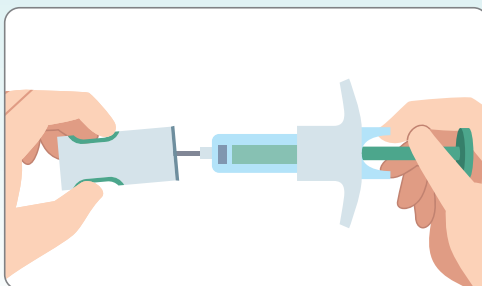
Grasp the finger grip firmly with one hand and remove the cap by pulling the cap straight off with the other hand.



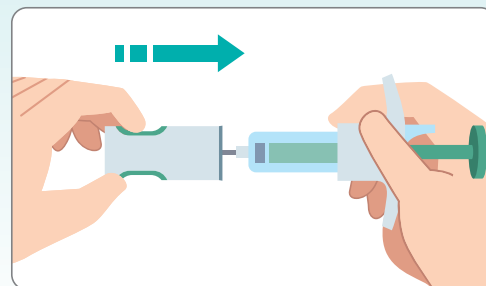
Precautions when removing the cap



X Do not twist when removing the cap.



X Do not hold the plunger rod.



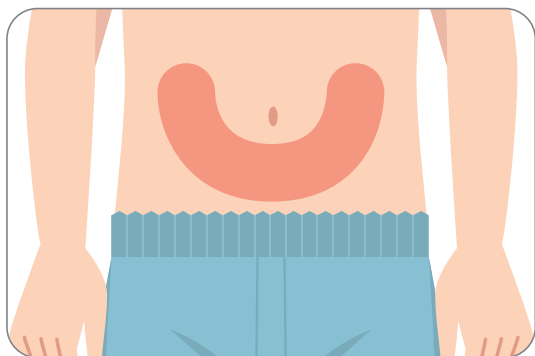
X Do not put back the cap once removed.

How to Inject Bimzelx[®]

[For Injection in the Abdomen] (1)

● Injection site

Sit on a chair, etc. in a relaxed position.



**Avoid the area around the navel
(about 5 cm)**

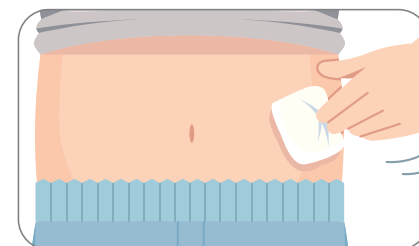
● How to inject

- Inject at a site different from the previous injection.
- When two syringes are administered in one dose, the sites of the two injections should be at least 3 cm apart.

1 Disinfect the injection site (skin) with an alcohol pad.

Wipe in a circular motion from the center outward, and dry well.

Do not touch the disinfected area until injection.



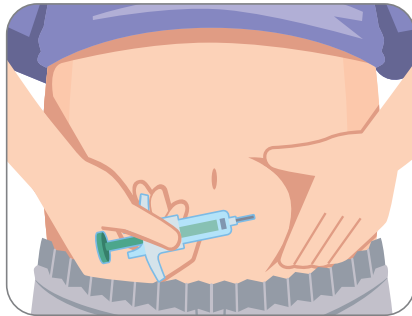
2 Remove the cap safely and cleanly.

Grasp the finger grip firmly with one hand and remove the cap by pulling the cap straight off with the other hand.

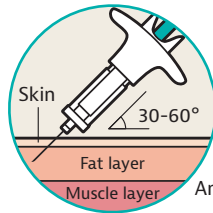
Once the cap is removed, inject as soon as possible.

How to Inject Bimzelx[®] [For Injection in the Abdomen] (2)

3 Insert the needle.

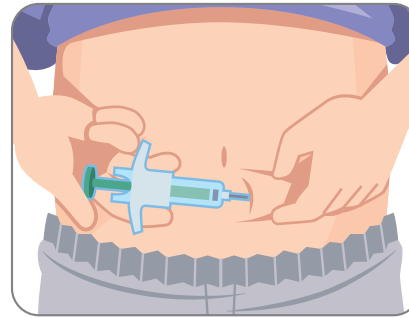


Gently pinch the skin at the injection site with one hand. Hold the finger grip with the other hand and insert the needle diagonally into the injection site.



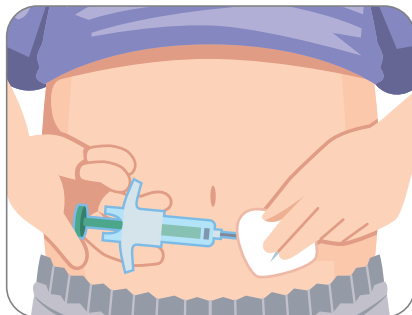
Angle of the needle

4 Inject.



Press the head with your finger and slowly inject the drug solution. When the head stops moving, the injection is complete.

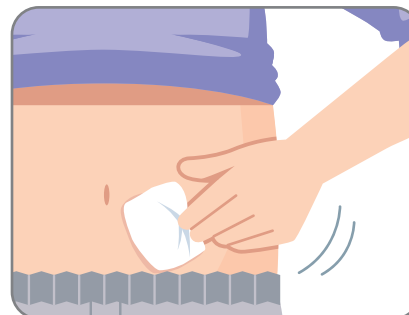
5 Pull out the needle.



When the injection is complete, pull the needle straight out while holding the head. If you release your finger from the head, the injection needle will be retracted into the main unit, which is then automatically locked to prevent accidental needle sticks.

Do not remove your finger from the head before pulling out the needle.

6 Gently press and confirm that bleeding has stopped



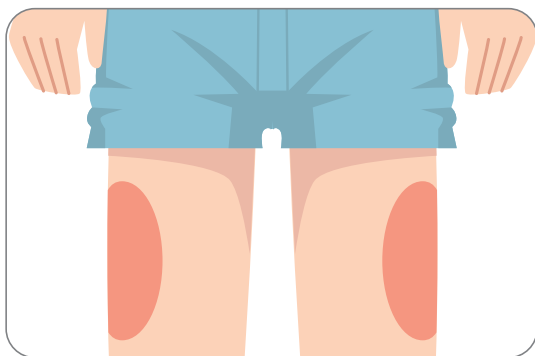
Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

Do not rub the injection site.

How to Inject Bimzelx[®] [For Injection in the Thighs] (1)

● Injection site

Sit on a chair, etc. in a relaxed position.



Avoid areas 5 cm above the knee joint and 5 cm below the groin.

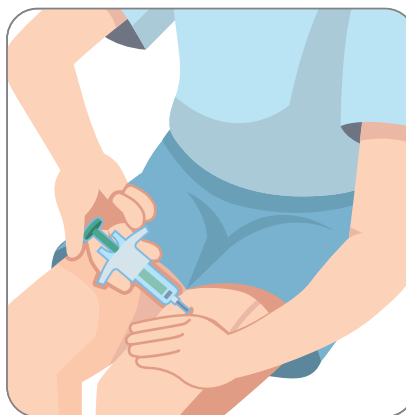
● How to inject

1 Disinfect the injection site (skin) with an alcohol swab.

2 Remove the cap safely and cleanly.

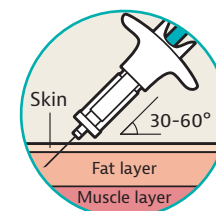
3 Pinch the skin and insert the needle diagonally.

- Inject at a site different from the previous injection.
- When two syringes are administered in one dose, the sites of the two injections should be at least 3 cm apart.



The angle of the injection needle is 30 to 60 degrees.

Please check with your doctor or nurse about the angle to insert the needle.

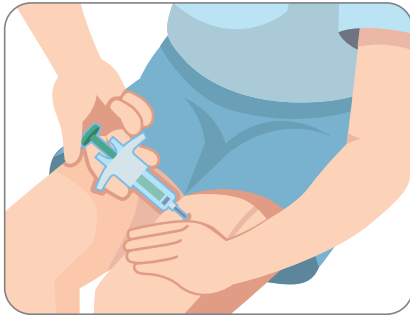


Angle of the needle

How to Inject Bimzelx[®]

[For Injection in the Thighs] (2)

4 Inject.



Press the head with your finger and slowly inject the drug solution. When the head stops moving, the injection is complete.

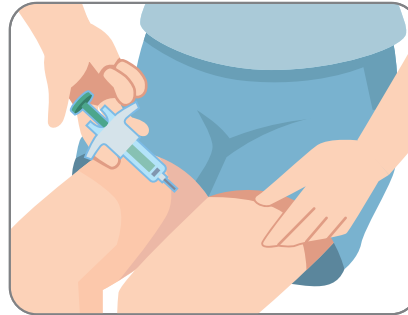
6 Gently press and confirm that bleeding has stopped.



Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

Do not rub the injection site.

5 Pull out the needle.



When the injection is complete, pull the needle straight out while holding the head. If you release your finger from the head, the injection needle will be retracted into the main unit, which is then automatically locked to prevent accidental needle sticks.

Do not remove your finger from the head before pulling out the needle.

For Injection by Persons Other Than the Patient (1)

● Injection sites / How to inject

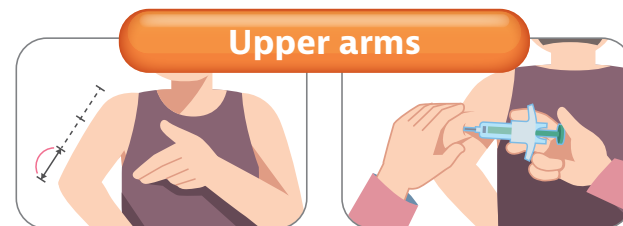
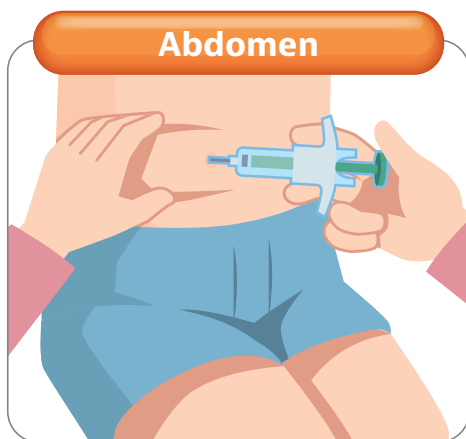
Even if the injection is given by any person other than you, be sure to receive guidance on how to inject Bimzelx®.

1 Disinfect the injection site (skin) with an alcohol pad.

2 Remove the cap safely and cleanly.

3 Pinch the skin and insert the needle diagonally.

- Inject at a site different from the previous injection.
- When two syringes are administered in one dose, the sites of the two injections should be at least 3 cm apart.

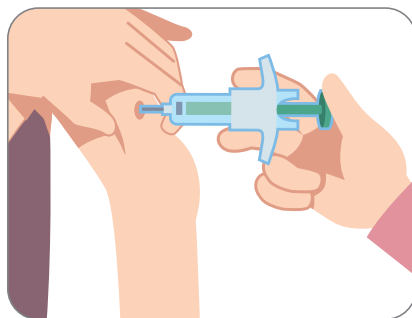


- Have the patient bend the arm at a 90-degree angle and support it with the other hand, or stabilize the arm by putting the hand on the hip.
- When the length from the tip of the shoulder to the tip of the elbow is divided into equal thirds, the position at about the first third from the tip of the elbow is the injection site.
- Inject into the back side of the upper arm.

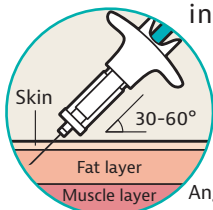
For Injection by Persons Other Than the Patient (2)

● How to inject Bimzelx® [for injection in the upper arms]

1 Pinch the skin and insert the needle.

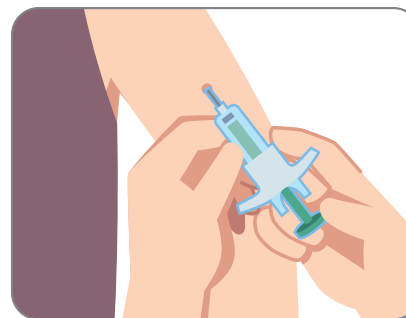


Gently pinch the skin at the injection site with one hand. Hold the finger grip with the other hand, insert the needle into the injection site, and release the pinched skin.



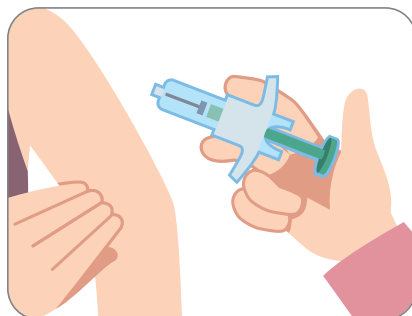
Angle of the needle

2 Inject.



Press the head with your finger and slowly inject the drug solution. When the head stops moving, the injection is complete.

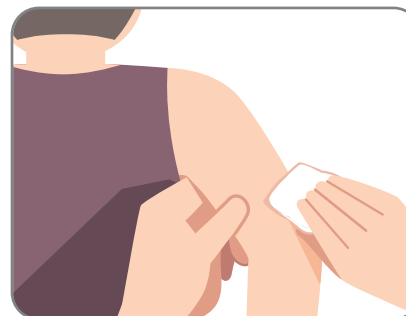
3 Pull out the injection needle.



When the injection is complete, pull the needle straight out while holding the head. If you release your finger from the head, the injection needle will be retracted into the main unit, which is then automatically locked to prevent accidental needle sticks.

Do not remove your finger from the head before pulling out the needle.

4 Gently press and confirm that bleeding has stopped.

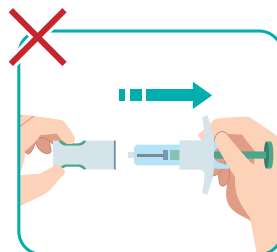


Gently press an alcohol pad over the injection site for several seconds. Confirm that bleeding has stopped, and the injection is complete.

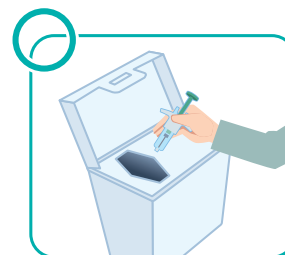
Do not rub the injection site.

Cleanup

- Do not recap the syringe after injection.
- Dispose of alcohol pads and caps as household waste unless otherwise specified.
- Put the used syringes in the dedicated disposal box, keep it in a place out of reach of children, and dispose of it as directed by the medical institution.
- Do not dispose of used syringes as household waste.



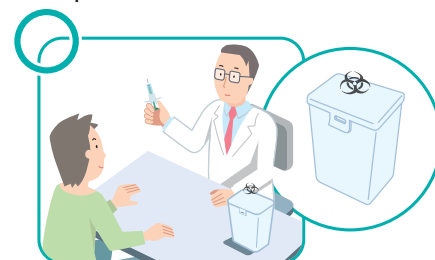
Do not recap.



Put in the dedicated disposal box.



Alcohol pads and caps are household waste.



Used syringes are medical waste.

Keep records.

Keep records from the day you start injecting Bimzelx®.

Please use the **BIMZELX® NOTE**.

It is useful for early detection of changes in the skin and joint conditions and adverse reactions.

Bring your **BIMZELX® NOTE** with you when you visit the medical institution and always show it to your doctor.



BIMZELX® NOTE

How to Reduce Injection Pain

- Please refer to the following tips and try to find strategies that work for you to reduce injection pain. These tips can be used for either the autoinjector or syringe.
 - Inject into a plump area having thick subcutaneous fat.
 - As a nervous state makes you more sensitive to pain, it is recommended to get yourself in a relaxed position and take deep breaths for alleviating pain before giving an injection.
 - Do not inject when the injection site remains wet after alcohol disinfection. Needle insertion into a wet site may cause smarting.
 - In general, injection of a cold drug solution is more likely to cause pain. Therefore, always return it to room temperature before injection.
 - To make the injection site less sensitive to pain, cool the injection site with a refrigerant for 1 to 2 minutes. After cooling, disinfect the site. Warming the injection site before injection may also help reduce pain.

Q&As about Self-Injection

About Bimzelx® in general

Q1 What time is the best for injection?

A1 You can inject at any time of the day. However, it is better to set a regular time to inject so that you do not forget it. Consult your doctor.

Q2 What should I do if I forget to inject a dose?

A2 Contact your doctor and follow the instruction provided.

Q3 What should I do if I am unable to inject on the scheduled injection date?

A3 If you know in advance that it will be difficult to inject due to traveling, etc., consult your doctor and follow the instruction provided.

Q4 How should I choose the injection site? Can I insert the needle into the same site every time?

A4 Avoid areas with skin symptoms (such as redness, rash, peeling scales, bumps, and hardness), injury, or pain. Inject at a site different from the previous injection. When receiving guidance on self-injection, have your doctor or nurse check your skin condition and consult.

Q5 Why is it necessary to return the drug solution to room temperature?

A5 Because injection of a cold drug solution is more likely to cause pain.

Q&As about Self-Injection

About Bimzelx® in general

Q6 What should I do about the storage location and temperature of the Bimzelx®? Is it acceptable to use Bimzelx® stored at deviated temperatures?

A6 Store the medicine received at a medical institution in the refrigerator (2-8°C), avoiding freezing, keeping it in the outer box so as not to be affected by light, until the time of injection. If the medicine is removed from the refrigerator, keeping it in the outer box at not more than 25°C so as not to be affected by light, use it within 30 days, not beyond the expiration date, and do not return it to the refrigerator again.

Q7 What measures can I take to prepare for disasters?

- A7**
- Consult your doctor and consider keeping spares.
 - Make the names of your disease, complications, and prescribed medicines easily accessible.
Try to keep the documents that indicate your treatment history and medical condition (for example, BIMZELX® NOTE and the medication certification card) with you. Keeping a medication note in your wallet or taking a photo of medicines with your cell phone are also helpful in case of emergency.
 - Prepare against power outage.
To store medicines requiring refrigeration, such as Bimzelx®, keep refrigerants frozen. However, never put Bimzelx® in the freezer or freeze it.

The image shows three overlapping Bimzelx® Medication Certification Cards. Each card is designed for a specific medical condition and includes a header for healthcare providers, a patient statement, a warning about immunosuppression, and a form for date and name.

- Top Card (Dry Eye Disease):** Header: 医師・薬剤師・看護師の方へ. Text: 私は乾癬治療のため、ビンゼレックス®による治療を受けています。ビンゼレックス®は免疫を抑制する作用があります。口腔や上気道などに感染症が起こる可能性がありますのでご注意ください。 Fields: 生年月日: , お名前: . Logo: uch Inspired by science.
- Middle Card (Rheumatoid Arthritis):** Header: 医師・薬剤師・看護師の方へ. Text: 私は体軸性脊椎関節炎治療のため、ビンゼレックス®による治療を受けています。ビンゼレックス®は免疫を抑制する作用があります。口腔や上気道などに感染症が起こる可能性がありますのでご注意ください。 Fields: 生年月日: , お名前: . Logo: uch Inspired by science.
- Bottom Card (Hidradenoma):** Header: 医師・薬剤師・看護師の方へ. Text: 私は化膿性汗腺炎治療のため、ビンゼレックス®による治療を受けています。ビンゼレックス®は免疫を抑制する作用があります。口腔や上気道などに感染症が起こる可能性がありますのでご注意ください。 Fields: 生年月日: , お名前: . Logo: uch Inspired by science. Additional text: 他の診療科・医療施設を受診する際、このカードを提示してください。

Bimzelx® Medication Certification Card

Q&As about Self-Injection

For autoinjector users

Q1 What should I do if I can't push the autoinjector (it doesn't move)?

A1 Put the autoinjector back in the box and contact your doctor, nurse, or pharmacist.

Q2 What should I do if the autoinjector is activated before placing it on the body?

A2 If the autoinjector is accidentally activated, the drug solution will flow out until it runs out. Do not try to stop the flow of the drug solution and leave it as it is until it runs out, without touching it. Discontinue the injection and contact and consult your doctor.

Q3 What should I do if I detach the autoinjector from the body before the injection is complete?

A3 When you detach the autoinjector from the body, the needle guard will cover the needle, which is then locked. The drug solution will continue to flow out until it runs out, but do not try to stop the flow of the drug solution and leave it as it is until it runs out, without touching it. Discontinue the injection and contact and consult your doctor.

Q4 Is the needle invisible?

A4 The needle is not visible because the needle tip of the autoinjector is covered by the needle guard.

Q&As about Self-Injection

For syringe users

Q1 What should I do if I accidentally prick my finger with the needle of the syringe?

A1 Do not inject with that syringe again. Check the amount of the drug solution remaining in the syringe and contact and consult your doctor.

Q2 What should I do if the needle comes off from the skin during injection?

A2 Do not inject with that syringe again. Check the amount of the drug solution remaining in the syringe and contact and consult your doctor.

● Introduction of a self-injection training video

This video explains the procedures and key points for self-injecting Bimzelx® safely and correctly. For details, please scan the QR codes below.

Autoinjector

160 mg injection



320 mg injection



Syringe

160 mg injection



Emergency Contact:

For inquiries about our products, please contact the following:

UCBCares®

UCBCares® Contact Center

Tel: 0120-093-189

Business hours: 9:00 a.m.–5:30 p.m.

(excluding Saturdays, Sundays, national holidays, and company holidays)