

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Bimzelx[®]?

Bimzelx[®] contains the active ingredient bimekizumab. Bimzelx[®] is used to treat plaque psoriasis. Bimzelx[®] reduces the symptoms, including pain, itching, and scaling of the skin.

For more information, see Section [1. Why am I using Bimzelx[®]?](#) in the full CMI.

2. What should I know before I use Bimzelx[®]?

Do not use if you have ever had an allergic reaction to Bimzelx[®] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Bimzelx[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bimzelx[®] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Bimzelx[®]?

- Your healthcare professional should show you how to prepare and inject Bimzelx[®] using the pre-filled syringe or pen. **Do not** inject yourself or someone else until you have been shown how to inject Bimzelx[®] the right way.
- You and your caregiver should read [4. How do I use Bimzelx[®]?](#) before each use of Bimzelx[®].
- To receive your full dose, you will need to use 2 Bimzelx[®] pre-filled syringes or pens, one after the other.

More instructions can be found in Section [4. How do I use Bimzelx[®]?](#) in the full CMI.

5. What should I know while using Bimzelx[®]?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Bimzelx[®].Use the product once in one patient only and discard any residue after use.
Things you should not do	<ul style="list-style-type: none">Do not inject yourself with this medicine unless you have been trained by a healthcare professional.Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
Looking after your medicine	<ul style="list-style-type: none">Keep this medicine out of the sight and reach of children.Store in a refrigerator between 2°C – 8°C. Do not freeze. Keep in the outer carton to protect from light.Bimzelx[®] may be stored at room temperature (up to 25°C) for a single period of maximum 30 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 30 days or by the expiry date, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

For more information, see Section [5. What should I know while using Bimzelx[®]?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: Upper respiratory tract infections (sore throat and stuffy nose), thrush in mouth or throat, athlete's foot, cold sores, gastroenteritis (symptoms may include diarrhoea; nausea; vomiting; stomach pain; indigestion; decrease in appetite), inflamed hair follicles, headache, acne, redness, pain or swelling at the site of injection and feeling tired.

Serious side effects include: Serious infections - symptoms may include fever, flu like symptoms, night sweats, feeling tired or short of breath, cough which will not go away, warm, red and painful skin or a painful rash with blisters

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at

www.tga.gov.au/reporting-problems.

Bimzelx[®]

Active ingredient(s): *bimekizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bimzelx[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bimzelx[®].**

Where to find information in this leaflet:

- [1. Why am I using Bimzelx[®]?](#)
- [2. What should I know before I use Bimzelx[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Bimzelx[®]?](#)
- [5. What should I know while using Bimzelx[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Bimzelx[®]?

Bimzelx[®] contains the active ingredient bimekizumab. Bimzelx[®] belongs to a group of medicines called interleukin (IL) inhibitors. Bimekizumab works by reducing the activity of two proteins called IL-17A and IL-17F. There are higher levels of these proteins in diseases such as psoriasis.

Bimzelx[®] is used to treat a skin condition called plaque psoriasis. Bimzelx[®] reduces the symptoms, including pain, itching and scaling of the skin.

2. What should I know before I use Bimzelx[®]?

Warnings

Do not use Bimzelx[®] if:

- you are allergic to bimekizumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as ongoing infections or an infection that keeps coming back, tuberculosis, Crohn's disease or ulcerative colitis.
- take any medicines for any other condition.

- recently had or plan to have a vaccination. You should not be given certain types of vaccines, such as live vaccines while using Bimzelx[®].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Bimzelx[®] should be used in pregnancy only if the benefits clearly outweigh the potential risks.

Children and adolescents

Bimzelx[®] is not recommended for children and young people under 18 years of age. This is because it has not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bimzelx[®].

4. How do I use Bimzelx[®]?

How much to take / use

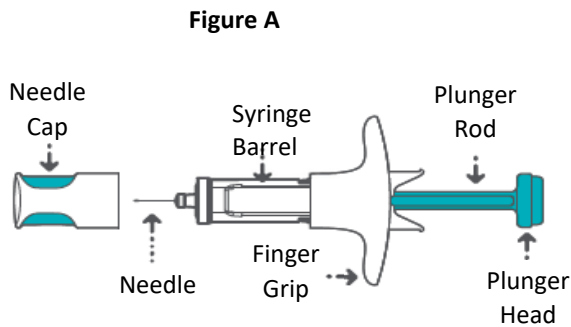
- The recommended dose, given as injections under your skin is as follows:
 - 320 mg (given as two pre-filled syringes or pens, containing 160 mg each) at Weeks 0, 4, 8, 12, 16.
 - From Week 16, you will use 320 mg given as two pre-filled syringes or pens, containing 160 mg each) every 8 weeks. If you weigh more than 120 kg, your doctor may decide to continue every 4 weeks from Week 16
- Follow the instructions provided and use Bimzelx[®] until your doctor tells you to stop.

When to take / use Bimzelx®

Bimzelx® should be used as instructed by your doctor.

How to Inject Bimzelx® pre-filled syringe

Bimzelx® pre-filled syringe at a glance (see figure A):



The Bimzelx® pre-filled syringe has a needle safety feature. This will be activated to cover the needle after the injection is finished. The needle safety feature will help to prevent the needle sticking into anyone who handles the pre-filled syringe after injection.

For a more comfortable injection: Take the Bimzelx® pre-filled syringe(s) carton(s) out of the refrigerator and let it (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.

Step 1: Setting up for your injections

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

- 2 Bimzelx® pre-filled syringes

You will also need (not included in the carton):

- 2 alcohol wipes
- 2 clean cotton balls
- 1 sharps disposal container.

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 injection site and prepare your injection

2a: Choose your injection site

- The places you may choose for your injection are:
 - your stomach (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

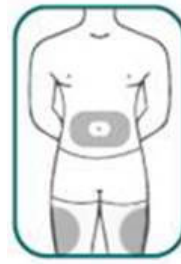
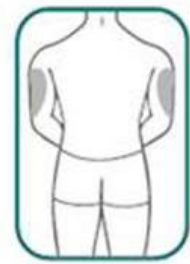


Figure C



- 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 5cm of the belly-button (navel)
- You should change where to inject with 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

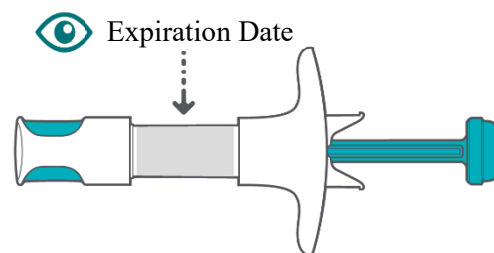
2c: Prepare your skin

- 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 expiration date appear on the label.
- Check the medicine through the viewing window. The medicine inside should be pale brownish-yellow and free of particles. You may see air bubbles in the liquid. This is normal.
- Do not use the Bimzelx® pre-filled syringe if the medicine is cloudy, discoloured, or has particles.

Figure D

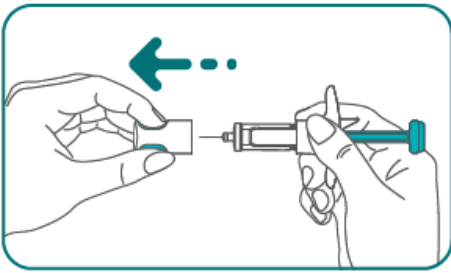


Step 3: Inject Bimzelx®

3a: Remove the pre-filled syringe needle cap

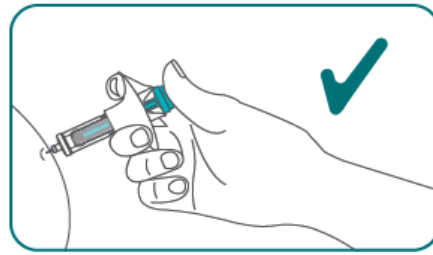
- Hold the pre-filled syringe around the finger grip with one hand. Pull the cap straight off the pre-filled syringe with the other hand (see **Figure E**). You may see a drop of liquid on the tip of the needle, this is normal.

Figure E



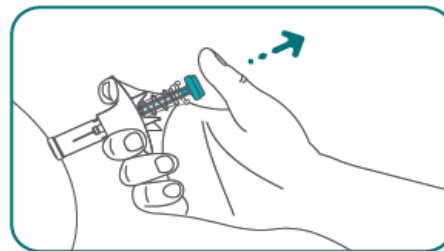
- **Do not** touch the needle or let the needle touch any surface.
- **Do not** hold the plunger rod during cap removal. If you accidentally remove the plunger rod, throw the pre-filled syringe in the sharps disposal container and get a new one.
- **Do not** put the needle cap back on. If you do, you could damage the needle or prick yourself by accident.

Figure H



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

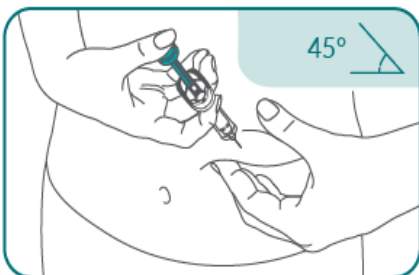
Figure I



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

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

Figure F



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

Figure G



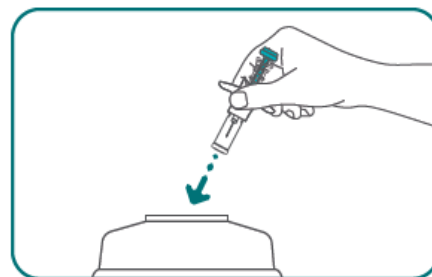
- All the medicine is injected when you cannot push the plunger head any further (see Figure H).

- 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 bandage, if needed.

Step 4: Throw away the used Bimzelx® pre-filled syringe

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

Figure J

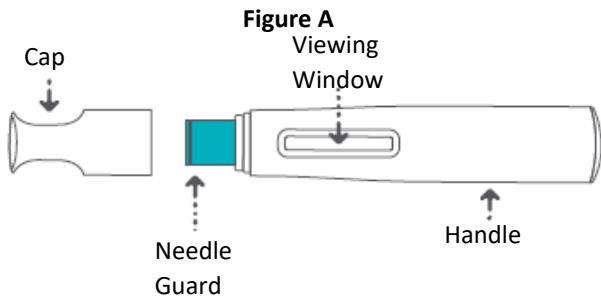


To receive the second injection of your prescribed dose, use a new Bimzelx® pre-filled syringe and repeat steps 2 to 4.

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

How to Inject Bimzelx® pre-filled pen

Bimzelx® pre-filled pen at a glance (see figure A):



For a more comfortable injection: Take the Bimzelx® pre-filled pen(s) carton(s) out of the refrigerator and let it (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.

Step 1: Setting up for your injections

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

- 2 Bimzelx® pre-filled pens

You will also need (not included in the carton):

- 2 alcohol wipes
- 2 clean cotton balls
- 1 sharps disposal container.

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 injection site and prepare your injection

2a: Choose your injection site

- The places you may choose for your injection are:
 - your stomach (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

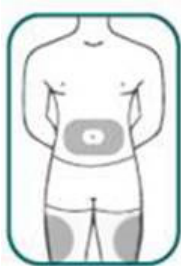
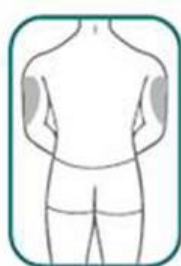


Figure C



- 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 5cm of the belly-button (navel)
- You should change where to inject with 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

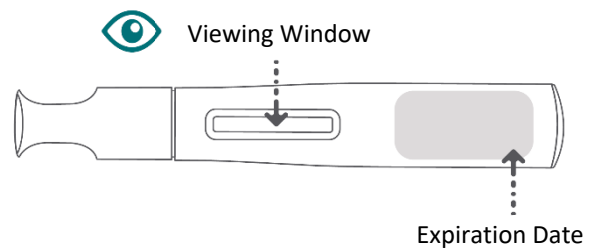
2c: Prepare your skin

- 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 expiration date appear on the label.
- Check the medicine through the viewing window. The medicine inside should be pale brownish-yellow and free of particles. 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.

Figure D

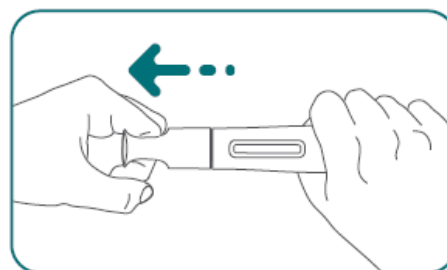


Step 3: Inject Bimzelx®

3a: Remove the pre-filled pen cap

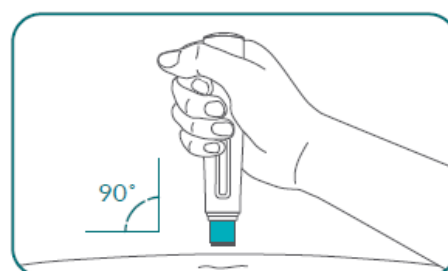
- Hold the pre-filled pen firmly with one hand around the handle. Pull the cap straight off the pre-filled pen with the other hand (see **Figure E**). Although you cannot see the needle tip, it is now uncovered.
- **Do not** touch the needle guard or put the cap back on. This is because it could activate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

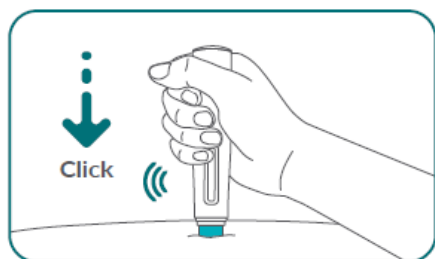
Figure F



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.

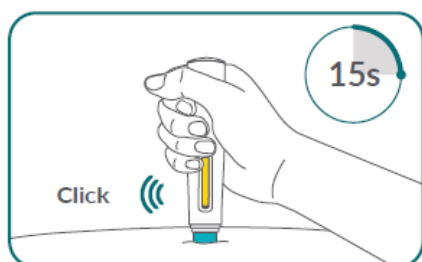
Figure G



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

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

Figure H



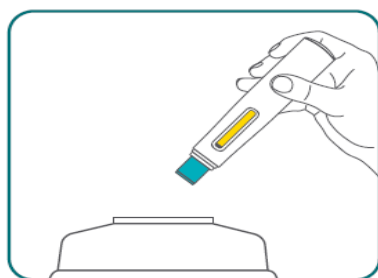
3e: Remove the pre-filled pen by carefully pulling it straight up from your skin. The needle guard will automatically cover the needle

- 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 drop of liquid. This is normal. You may cover the injection site with a small adhesive bandage, if needed.

Step 4: Throw away the used Bimzelx® pre-filled pen

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

Figure I



To receive 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.

If you forget to use Bimzelx®

If you miss your Bimzelx® dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Call your doctor if you are not sure what to do.

Do not take a double dose to make up for the dose you missed.

If you use too much Bimzelx®

If you think that you have used too much Bimzelx®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Bimzelx®?

Remind any doctor, dentist or pharmacist you visit that you are using Bimzelx®.

Things you should not do

- Do not inject yourself with this medicine unless you have been trained by a healthcare professional
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
- Do not use this medicine if the carton seal is broken.
- Do not use this medicine if the pre-filled syringe/pen has been dropped or looks damaged.
- Do not use this medicine if the liquid has ever been frozen (even if thawed).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Bimzelx® affects you.

Bimzelx® is not anticipated to have any influence on the ability to drive and use machines.

Looking after your medicine

- Store in a refrigerator between 2°C – 8°C.
- Do not freeze.
- Keep the pre-filled syringe or pen in the outer carton in order to protect from light.
- The Bimzelx® pre-filled syringe and pre-filled pen may be stored at room temperature (up to 25°C) for a single period of maximum 30 days with protection

from light. Once removed from the refrigerator and stored under these conditions, discard after 30 days or by the expiry date, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard after the expiry date, or 30 days after removed from the refrigerator.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Infection:</p> <ul style="list-style-type: none"> upper respiratory infections with symptoms such as sore throat and stuffy nose cold sores thrush in mouth or throat inflamed hair follicles acne athlete's foot <p>Injection site reactions:</p> <ul style="list-style-type: none"> redness, pain or swelling at the site of injection <p>Stomach and gut:</p> <ul style="list-style-type: none"> gastroenteritis (symptoms may include diarrhoea, nausea, vomiting, stomach pain, indigestion, decrease in appetite) <p>General:</p> <ul style="list-style-type: none"> headache feeling tired 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do

Serious infections, symptoms may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Allergic reaction:

- difficulty breathing or swallowing
- low blood pressure, which can make you dizzy or light-headed
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Bimzelx® contains

Active ingredient (main ingredient)	Bimekizumab
Other ingredients (inactive ingredients)	glycine, sodium acetate trihydrate, acetic acid, polysorbate 80 and water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Bimzelx® looks like

Bimzelx® is a clear to slightly opalescent and pale brownish-yellow liquid. It comes in a single use disposable pre-filled syringe or pen.

Bimzelx® is available in unit packs containing 2 pre-filled syringes/pens. (AUST R 353269/353268).

Who distributes Bimzelx®

UCB Pharma

A division of UCB Australia Pty Ltd

Level 1, 1155 Malvern Road

Malvern VIC 3144, Australia

This leaflet was prepared in March 2022