

Package leaflet: Information for the user

Bimzelx 320 mg solution for injection in pre-filled pen bimekizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bimzelx is and what it is used for
 2. What you need to know before you use Bimzelx
 3. How to use Bimzelx
 4. Possible side effects
 5. How to store Bimzelx
 6. Contents of the pack and other information
- Instructions for use

1. What Bimzelx is and what it is used for

What Bimzelx is

Bimzelx contains the active substance bimekizumab.

What Bimzelx is used for

Bimzelx is used to treat the following inflammatory diseases:

- Plaque psoriasis
- Psoriatic arthritis
- Axial spondyloarthritis, including non-radiographic axial spondyloarthritis and ankylosing spondylitis (radiographic axial spondyloarthritis)
- Hidradenitis suppurativa

Plaque psoriasis

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

Psoriatic arthritis

Bimzelx is used to treat adults with psoriatic arthritis. Psoriatic arthritis is a disease that causes inflamed joints, often accompanied by plaque psoriasis. If you have active psoriatic arthritis, you may first be given other medicines. If these medicines do not work well enough or in case of intolerance, you will be given Bimzelx either alone or in combination with another medicine called methotrexate.

Bimzelx reduces inflammation and can therefore help to reduce pain, stiffness, swelling in and around your joints, psoriatic skin rash, psoriatic nail damage and slow down the damage to the cartilage and bone of the joints involved in the disease. These effects can help you to control signs and symptoms of the disease, ease your normal daily activities, reduce tiredness, and improve your quality of life.

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

Bimzelx is used to treat adults with an inflammatory disease primarily affecting the spine which causes inflammation of the spinal joints, called axial spondyloarthritis. 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”.

If you have axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Bimzelx to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function. Bimzelx can help to reduce back pain, stiffness and tiredness, which can ease your normal daily activities and improve your quality of life.

Hidradenitis suppurativa

Bimzelx is used in adults to treat a condition called hidradenitis suppurativa (sometimes called acne inversa or Verneuil’s disease). Hidradenitis suppurativa is a chronic inflammatory skin disease that causes painful lesions like tender nodules (lumps) and abscesses (boils), and lesions that may leak pus. It most commonly affects specific areas of the skin such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas. You will first be given other medicines. If you do not respond well enough to these medicines, you will be given Bimzelx.

Bimzelx reduces the inflammatory nodules (lumps), abscesses (boils), and lesions that may leak pus, as well as pain caused by hidradenitis suppurativa.

How Bimzelx works

Bimekizumab, the active substance in 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, which are involved in causing inflammation. There are higher levels of these proteins in inflammatory diseases such as psoriasis, psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa.

2. What you need to know before you use Bimzelx

Do not use Bimzelx

- if you are allergic to bimekizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including tuberculosis (TB), which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Bimzelx if:

- you have an infection or an infection that keeps coming back.
- you recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Bimzelx.
- you have ever had tuberculosis (TB).
- you have ever had inflammatory bowel disease (Crohn’s disease or ulcerative colitis).

Inflammatory bowel disease (Crohn’s disease or ulcerative colitis)

Stop using Bimzelx and tell your doctor or get medical help immediately if you notice blood in the stool, abdominal cramps, pain, diarrhoea or weight loss. These may be signs of new or worsening inflammatory bowel disease (Crohn’s disease or ulcerative colitis).

Look out for infections and allergic reactions

Bimzelx can rarely cause serious infections. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious infection. Such signs are listed under “Serious side effects” in section 4.

Bimzelx can potentially cause serious allergic reactions. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious allergic reaction. Such signs may include:

- 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.

Children and adolescents

Do not give this medicine to children and young people under 18 years of age. This is because it has not been studied in this age group.

Other medicines and Bimzelx

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Bimzelx in pregnancy. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 17 weeks after your last dose of Bimzelx.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you can breast-feed or use Bimzelx.

Driving and using machines

Bimzelx is unlikely to affect your ability to drive and use machines.

Bimzelx contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially “sodium free”.

3. How to use Bimzelx

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Bimzelx is given and for how long

Plaque psoriasis

The recommended dose, given as an injection under your skin (‘subcutaneous injection’) is as follows:

- 320 mg (given as **one** pre-filled pen containing 320 mg) at weeks 0, 4, 8, 12, 16.
- From week 16, you will use 320 mg (**one** pre-filled pen containing 320 mg) every 8 weeks. If you weigh more than 120 kg, your doctor may decide to continue your injections every 4 weeks from week 16.

Psoriatic arthritis

The recommended dose, given as an injection under your skin ('subcutaneous injection') is as follows:

- 160 mg every 4 weeks.
- If you have psoriatic arthritis with coexistent moderate to severe plaque psoriasis, the recommended dose regimen is the same as for plaque psoriasis. After week 16, your doctor may adapt your injections to 160 mg every 4 weeks, depending on your joint symptoms. Other pharmaceutical forms /strengths are available for administration of the 160 mg dose.

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

The recommended dose, given as an injection under your skin ('subcutaneous injection') is as follows:

- 160 mg every 4 weeks. Other pharmaceutical forms/strengths are available for administration of the 160 mg dose.

Hidradenitis suppurativa

The recommended dose, given as an injection under your skin ('subcutaneous injection') is as follows:

- 320 mg (given as **one** pre-filled pen containing 320 mg) every 2 weeks until week 16.
- From week 16, you will use 320 mg (**one** pre-filled pen containing 320 mg) every 4 weeks.

You and your doctor or nurse will decide if you should inject this medicine yourself. Do not inject this medicine unless you have been trained by a healthcare professional. A caregiver may also give your injections after they have been trained.

Read the '**Instructions for use**' at the end of this leaflet before injecting Bimzelx 320 mg solution for injection in pre-filled pen yourself.

If you use more Bimzelx than you should

Tell your doctor if you have used more Bimzelx than you should or if you have injected your dose earlier than you should.

If you forget to use Bimzelx

Talk to your doctor if you have forgotten to inject a dose of Bimzelx.

If you stop using Bimzelx

Talk to your doctor before you stop using Bimzelx. If you stop treatment, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or get medical help **immediately** if you get any of the following side effects:

Possible serious infection – the signs 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

Your doctor will decide if you can keep using Bimzelx.

Other side effects

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- thrush in the mouth or throat with symptoms such as white or yellow patches; red or sore mouth and pain with swallowing
- fungal infection of the skin, such as athlete's foot between the toes
- ear infections
- cold sores (herpes simplex infections)
- stomach flu (gastroenteritis)
- inflamed hair follicles which may look like pimples
- headache
- itchy, dry skin or an eczema-like rash sometimes with swollen and reddened skin (dermatitis)
- acne
- redness, pain or swelling and bruising at the site of injection
- feeling tired
- fungal infection of the vulvovaginal area (vaginal thrush)

Uncommon (may affect up to 1 in 100 people)

- lowered levels of white blood cells (neutropenia)
- fungal infections of the skin and mucous membranes (including oesophageal candidiasis)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- blood in the stool, abdominal cramps and pain, diarrhoea or weight loss (signs of bowel problems)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bimzelx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator between 2 °C and 8 °C. Do not freeze.

Keep the pre-filled pens in the original carton in order to protect from light.

Bimzelx can be kept out of the refrigerator for up to 25 days. This must be in the outer carton, not above 25 °C and away from direct light. Do not use the pre-filled pens after this time period. There is a space on the box so you can write the date it was taken out of the refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bimzelx contains

- The active substance is bimekizumab. Each pre-filled pen contains 320 mg of bimekizumab in the 2 mL solution.
- The other ingredients are glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80 and water for injections.

What Bimzelx looks like and contents of the pack

Bimzelx is a clear to slightly opalescent liquid. Its colour may vary from colourless to pale brownish-yellow. It comes in a single use disposable pre-filled pen.

Bimzelx 320 mg solution for injection in pre-filled pen is available in unit packs containing 1 pre-filled pen and in multipacks comprising 3 cartons, each containing 1 pre-filled pen.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB Pharma Limited
208 Bath Road
Slough
Berkshire
SL1 3WE, United Kingdom.

Manufacturer

UCB Pharma S.A.
Chemin du Foriest
B-1420 Braine-l'Alleud, Belgium

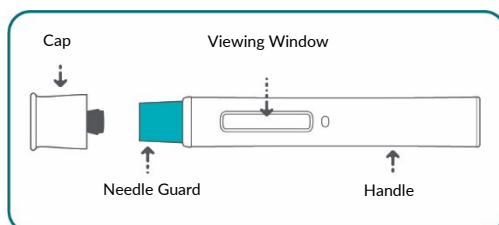
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Instructions for use

Read all the instructions below before you use Bimzelx 320 mg solution for injection in pre-filled pen.

Bimzelx 320 mg pre-filled pen at a glance (see **Figure A**):

Figure A



Important information:

- Your healthcare professional should show you how to prepare and inject Bimzelx using the 320 mg pre-filled pen. **Do not** inject yourself or someone else until you have been shown how to inject Bimzelx the right way.
- You and/or your caregiver should read these Instructions for Use before each use of Bimzelx.

- Call your healthcare professional if you or your caregiver have any questions about how to inject Bimzelx the right way.
- Each pre-filled pen is for one-time (single-dose) use only.

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

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

For a more comfortable injection: Take the 320 mg pre-filled pen out of the refrigerator and let it sit on a flat surface at room temperature in its original carton 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 pen.
- Do not uncap the pre-filled pen until you are ready to inject.

Follow the steps below each time you use Bimzelx.

Step 1: Setting up for your injection

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

- 1 Bimzelx 320 mg pre-filled pen

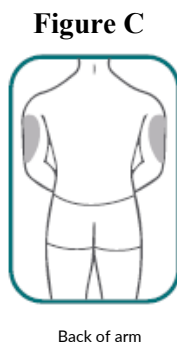
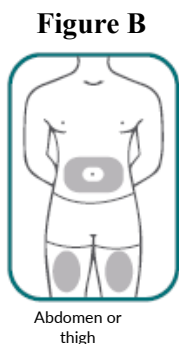
You will also need (not included in the carton):

- 1 alcohol wipe
- 1 clean cotton ball
- 1 sharps disposal container. See “Throw away the used Bimzelx pre-filled pen” at the end of these Instructions for Use.

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 (see **Figure C**). Bimzelx may be injected into the back of your arm by a healthcare professional or caregiver only.



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly-button (navel).

- You should choose a different place each time you give yourself an injection.

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

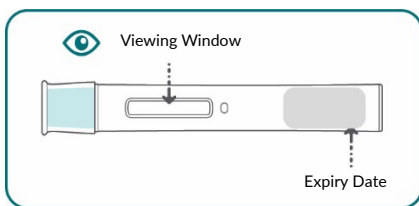
2c: Prepare your skin

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

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

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

Figure D

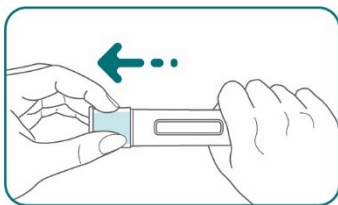


Step 3: Inject Bimzelx

3a: Remove the pre-filled pen cap

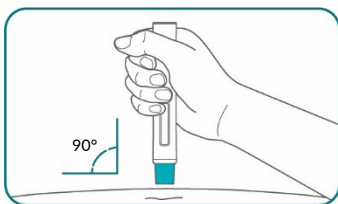
- Hold the pre-filled pen firmly with one hand around the handle. Pull the cap straight off the pre-filled pen with the other hand (see Figure E). Although you cannot see the needle tip, it is now uncovered.
- Do not touch the needle guard or put the cap back on. This is because it could activate the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

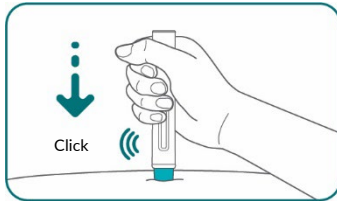
Figure F



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. It will take about 20 seconds to receive your full dose.

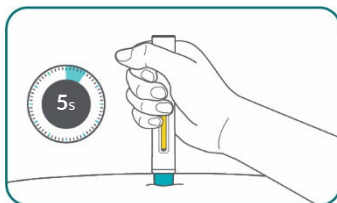
- You will hear a second “click” that tells you that the injection is **almost complete**. You will see the yellow colour indicator filling the viewing window (see **Figure H**).

Figure H



- **After the second click, continue to hold down the pre-filled pen for an additional 5 seconds (slowly count to 5). This will ensure you receive your full dose (see Figure I).**

Figure I



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

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

Step 4: 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 J**).

Figure J

