

Patient leaflet in accordance with the Pharmacists' Regulations **(Medicinal Products) - 1986**

This medicine is dispensed with a doctor's prescription only

BIMZELX® 160mg/ml

Solution for subcutaneous injection

Active ingredient:

Each pre-filled pen contains 160mg of bimekizumab in 1 ml.

For the list of excipients in the medicinal product, please see section 6: "Additional information".

Read the entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, contact the physician or the pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Bimzelx is indicated for the treatment of the following inflammatory diseases:

- Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy
- Active psoriatic arthritis alone or in combination with a conventional non-biologic disease-modifying antirheumatic drug (cDMARD) (e.g., methotrexate), in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
- Adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)

Therapeutic group: Immunosuppressants, interleukin 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 and axial spondyloarthritis.

2. Before using this medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient bimekizumab or any of the other ingredients that this medicine contains (see section 6).
- You have an infection, including tuberculosis (TB), which your doctor thinks is important.

Special warnings regarding the use of this medicine:

Before taking Bimzelx, tell your doctor 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. There is no data concerning safety and efficacy of this product in children and adolescents.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

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 has no or negligible influence on the ability to drive and use machines.

Important information regarding some of the ingredients of the medicine:

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

3. How to use the medicine?

Always use the medicinal product according to the doctor's instructions.

Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.

The dosage and treatment regimen will be determined only by the doctor.

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

Plaque psoriasis

- 320 mg (given as **two** pre-filled pens, containing 160 mg each) at weeks 0, 4, 8, 12, 16.
- From week 16, you will use 320 mg (**two** pre-filled pens, containing 160 mg each) every 8 weeks. If you weigh more than 120 kg, your doctor may decide to continue your injections every 4 weeks.

Psoriatic arthritis

- 160 mg (given as **one** pre-filled pen containing 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.

Ankylosing spondylitis and Non-radiographic axial spondyloarthritis

- 160 mg (given as **one** pre-filled pen containing 160 mg) every 4 weeks.

Do not exceed the recommended dose.

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 pre-filled pen yourself.

If you have accidentally taken a higher dosage

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 take the medicine

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

You should continue the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, Bimzelx can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

If a side effect appears, if any side effect gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

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 side effects - effects that appear in more than 1 user out of 10

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

Common side effects - effects that appear in 1-10 users out of 100

- 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 at the site of injection.
- feeling tired.
- fungal infection of the vulvovaginal area (vaginal thrush)

Uncommon side effects - effects that appear in 1-10 users out of 1000

- 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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: <https://sideeffects.health.gov.il/> and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without specific instruction from the doctor.

Do not use the medicine after the expiration date (exp. date) appearing on the packaging. The expiration date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

The pre-filled pen may be stored at room temperature (below 25°C) for a single period of maximum 25 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 25 days or by the expiry date printed on the container, whichever occurs first. 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. Additional information

In addition to the active ingredient, the medicine also contains:

glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80 and water for injections.

What does the medicine look like and the contents of the package:

Bimzelx is a clear to slightly opalescent and colourless to pale brownish-yellow solution. It comes in a single use disposable pre-filled pen.

Bimzelx is available in unit packs containing 2 pre-filled pens.

Manufacturer: UCB Pharma S.A., Braine l'Alleud, Belgium.

Registration Holder: Neopharm Ltd., Hashiloach 6 St., POB 7063, Petach-Tikva 4917001.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
172-46-37409-00

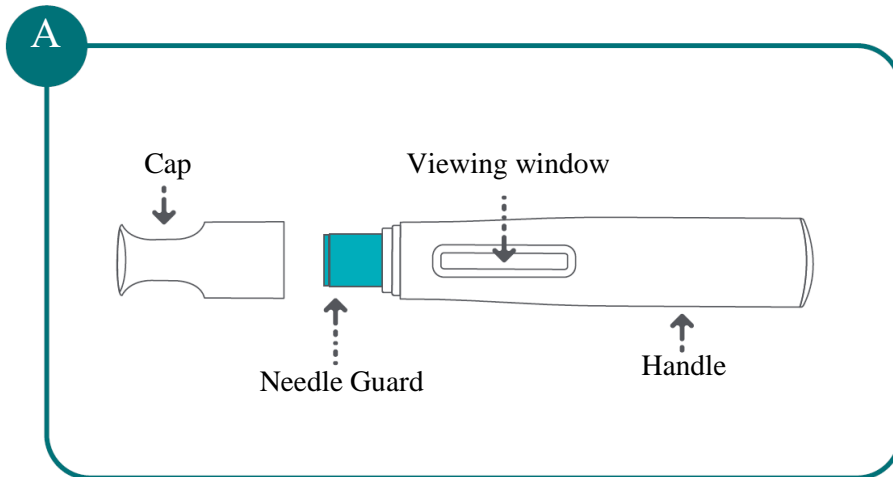
Revised in September 2024.

Bimzelx sol for inj PIL vr 03B

Instructions for use

Read all the instructions below before you use Bimzelx.

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



Important information:

- Your healthcare professional should show you how to prepare and inject Bimzelx using the pre-filled pen. **Do not** inject yourself or someone else until you have been shown how to inject Bimzelx the right way.
- You and/or your caregiver should read these Instructions for Use before each use of Bimzelx.
- Contact the healthcare professional if you or your caregiver have any questions about how to inject Bimzelx the right way.
- **Depending on your prescribed dose, you will need to use 1 or 2 Bimzelx pre-filled pen(s)**, One pre-filled pen is needed for a 160 mg dose and 2 pre-filled pens (one after the other) are needed for a 320 mg dose..

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 Bimzelx pre-filled pen(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 pen(s).
- Do not uncap the pre-filled pen(s) until you are ready to inject.

Follow the steps below each time you use Bimzelx.

Step 1: Setting up for your injection(s)

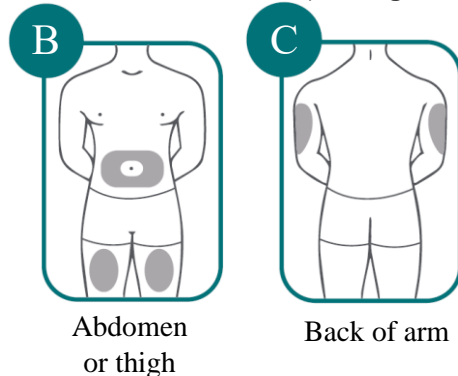
Depending on your prescribed dose, place the following items on a clean flat, well-lit work surface, like a table:

- 1 or 2 Bimzelx pre-filled pen(s)
- You will also need (not included in the carton):
- 1 or 2 alcohol wipe(s)
 - 1 or 2 clean cotton ball(s)
 - 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 may also be used if a caregiver is giving you the injection (**see Figure C**).



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly-button (navel).
- If a second injection is needed for your prescribed dose (320 mg), you should use a different place for your second injection. Do not use the same place to inject twice in a row.

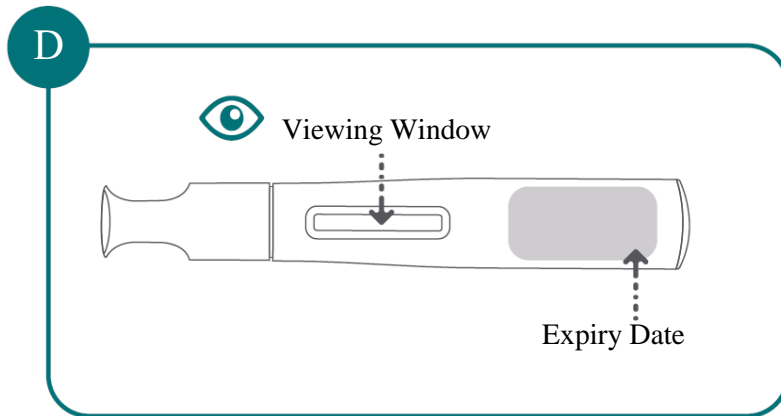
2b: Wash your hands well with soap and water and dry with a clean towel

2c: Prepare your skin

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

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

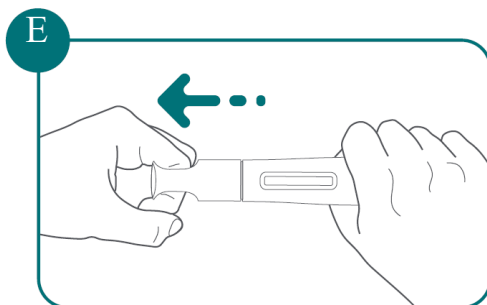
- Make sure the name Bimzelx and expiry date appear on the label.
- Check the medicine through the viewing window. Bimzelx is a clear to slightly opalescent and colourless to pale brownish-yellow solution. You may see air bubbles in the liquid. This is normal.
- Do not use Bimzelx pre-filled pen if the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



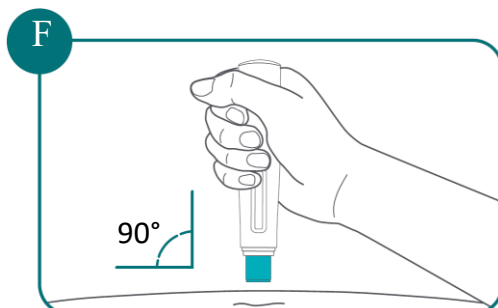
Step 3: Inject Bimzelx

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.



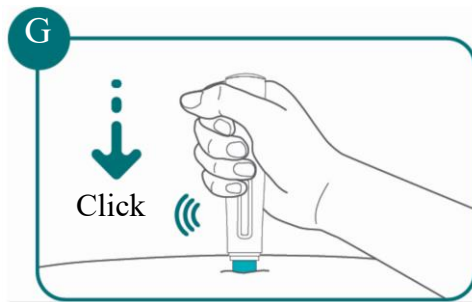
3b: Hold the pre-filled pen at a 90 degree angle to the cleaned injection site (see Figure F)



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

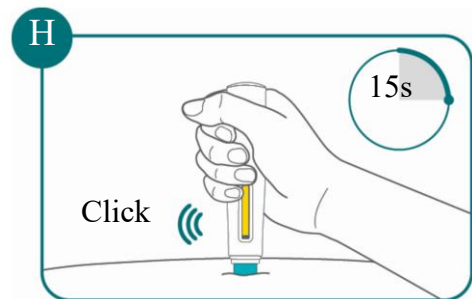
You will hear a click sound. Your injection begins when the first “click” is heard (**see Figure G**).

Do not lift the pre-filled pen away from the skin.



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

- You will hear a second “click” within 15 seconds after the first click.
- The second click tells you that all the medicine has been injected and your Bimzalex injection is finished. You should see the yellow colour indicator filling the viewing window (**see Figure H**).

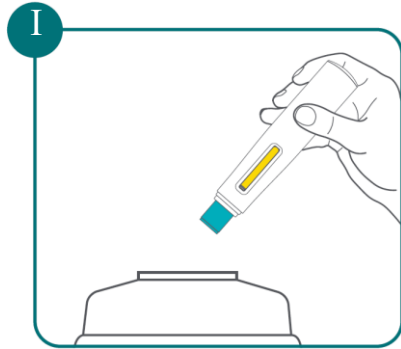


3e: Remove the pre-filled pen by carefully pulling it straight up from your skin. The needle guard will automatically cover the needle

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

Step 4: 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**).



If you need to have a second injection as prescribed by your doctor, 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.