

MEDICATION GUIDE

BIMZELX® (bim zel'ex)

(bimekizumab-bkzx)

injection, for subcutaneous use

What is the most important information I should know about BIMZELX?

BIMZELX is a medicine that affects your immune system. BIMZELX may increase your risk of having serious side effects, including:

- **Suicidal thoughts and behavior. New or worsening suicidal thoughts and behavior have happened in some people treated with BIMZELX.** Get medical help right away or call the National Suicide and Crisis Lifeline at 988 if you, your caregiver or your family member notice in you any of the following symptoms:
 - new or worsening depression or anxiety
 - thoughts of suicide, dying, or hurting yourself
 - changes in behavior or mood
 - acting on dangerous impulses
 - attempt to commit suicide
- **Infections.** BIMZELX is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections, including serious infections.
 - Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with BIMZELX.
 - If your healthcare provider feels you are at risk for TB, you may be treated with medicine for TB before you begin treatment with BIMZELX and during your treatment with BIMZELX.
 - Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with BIMZELX. **Do not take BIMZELX if you have an active TB infection.**

Before starting BIMZELX, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:
 - fever, sweats, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in your phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body different from your psoriasis
 - diarrhea or stomach pain
 - burning when you urinate or urinating more often than normal

After starting BIMZELX, call your healthcare provider right away if you have any of the signs of infection listed above. Do not use BIMZELX if you have any signs of infection unless you are instructed to by your healthcare provider.

See “**What are the possible side effects of BIMZELX?**” for more information about side effects.

What is BIMZELX?

BIMZELX is a prescription medicine used to treat:

- adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet light alone or with pills (phototherapy).
- adults with active psoriatic arthritis.
- adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- adults with active ankylosing spondylitis.
- adults with moderate to severe hidradenitis suppurativa.

It is not known if BIMZELX is safe and effective in children.

Before using BIMZELX, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about BIMZELX?”**
- have a history of depression, or suicidal thoughts or behavior
- have liver problems
- have inflammatory bowel disease (Crohn’s disease or ulcerative colitis)
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with BIMZELX. Tell all your healthcare providers that you are being treated with BIMZELX before receiving a vaccine.
- are pregnant or plan to become pregnant. It is not known if BIMZELX can harm your unborn baby.
 - If you become pregnant while taking BIMZELX, you are encouraged to enroll in the Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-877-311-8972 to enroll in this registry or visit <http://mothertobaby.org/pregnancy-studies/>.
- are breastfeeding or plan to breastfeed. It is not known if BIMZELX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with BIMZELX.

Tell your healthcare provider about all the medicines you take, including prescription and over the counter medicines, vitamins and herbal supplements.

How should I use BIMZELX?

See the detailed “Instructions for Use” that comes with your BIMZELX for information on how to prepare and inject a dose of BIMZELX, and how to properly throw away (dispose of) used BIMZELX autoinjectors and prefilled syringes.

- Use BIMZELX exactly as prescribed by your healthcare provider.
- 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 healthcare provider if you are not sure what to do.

What are the possible side effects of BIMZELX?

BIMZELX may cause serious side effects, including:

- **See “What is important information I should know about BIMZELX?”**
- **Elevated liver enzyme levels.** Your healthcare provider will do blood tests to check your liver enzyme levels before starting treatment and during treatment with BIMZELX. Your healthcare provider may temporarily stop or permanently stop your treatment with BIMZELX if you develop liver problems. Call your healthcare provider right away if you develop any signs or symptoms of liver problems, including:
 - pain on the right side of your stomach-area
 - feeling very tired
 - loss of appetite
 - nausea and vomiting
 - itching
 - dark urine
 - light-colored stool
 - yellowing of your skin or the whites of your eyes
- **Inflammatory bowel disease.** New cases of inflammatory bowel disease or “flare-ups” have happened with BIMZELX. If you have inflammatory bowel disease (Crohn’s disease or ulcerative colitis), tell your healthcare provider if you have worsening disease symptoms during treatment with BIMZELX or develop new symptoms of stomach pain or diarrhea. Your healthcare provider will stop treatment with BIMZELX if you develop new or worsening signs of Crohn’s disease or ulcerative colitis.

The most common side effects of BIMZELX in people treated for Psoriasis and Hidradenitis Suppurativa include:

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| • upper respiratory tract infections | • fungal infections (oral thrush or infections in the mouth, throat, skin, nails, feet or genitals) |
| • headache | • pain, redness or swelling at injection site |
| • herpes simplex infections (cold sores in or around the mouth) | • stomach flu (gastroenteritis) |
| • small red bumps on your skin | • acne |
| • feeling tired | |

The most common side effects of BIMZELX in people treated for psoriatic arthritis include:

- upper respiratory tract infections
- headache
- urinary tract infection
- oral thrush or infections in the mouth
- diarrhea

The most common side effects of BIMZELX in people treated for non-radiographic axial spondyloarthritis include:

- upper respiratory tract infections
- headache
- cough
- joint pain
- tonsillitis
- urinary tract infection
- oral thrush or infections in the mouth
- diarrhea
- feeling tired
- muscle aches
- liver enzyme increase

The most common side effects of BIMZELX in people treated for ankylosing spondylitis include:

- upper respiratory tract infections
- headache
- pain at injection site
- vaginal yeast infections
- oral thrush or infections in the mouth
- diarrhea
- rash

These are not all of the possible side effects of BIMZELX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BIMZELX?

- Store BIMZELX in the refrigerator between 36°F to 46°F (2°C to 8°C).
- BIMZELX may be stored at room temperature up to 77°F (25°C) for up to 30 days in the original carton. **Do not** place BIMZELX prefilled syringes or autoinjectors back in the refrigerator after they have been stored at room temperature.
- Write the date removed from the refrigerator in the space provided on the carton and throw away BIMZELX if it has been kept at room temperature and not been used within 30 days.
- Keep BIMZELX in the original carton until ready for use to protect from light.
- Do not freeze BIMZELX.
- Do not shake BIMZELX.
- Do not use BIMZELX past the expiration date printed on the carton.

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

General information about the safe and effective use of BIMZELX.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BIMZELX for a condition for which it was not prescribed. Do not give BIMZELX to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BIMZELX that is written for health professionals.

What are the ingredients in BIMZELX?

Active ingredient: bimekizumab-bkzx

Inactive ingredients: glacial acetic acid, glycine, polysorbate 80, sodium acetate and Water for Injection, USP.

Manufactured by:

UCB, Inc.

1950 Lake Park Drive Smyrna, GA 30080

US License No. 1736

For more information, go to www.BIMZELX.com or call 1-844-599-2273

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: November 2024