

BIMZELX- bimekizumab injection, solution

UCB, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BIMZELX safely and effectively. See full prescribing information for BIMZELX.

BIMZELX® (bimekizumab-bkzx) injection, for subcutaneous use
Initial U.S. Approval: 2023

INDICATIONS AND USAGE

BIMZELX is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. (1)

DOSAGE AND ADMINISTRATION

- Prior to treatment: (2.1)
 - Evaluate patients for tuberculosis infection.
 - Test liver enzymes, alkaline phosphatase, and bilirubin.
 - Complete all age-appropriate vaccinations as recommended by current immunization guidelines.
- Administer 320 mg (two 160 mg injections) by subcutaneous injection at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing \geq 120 kg, consider a dose of 320 mg every 4 weeks after Week 16. (2.2)

DOSAGE FORMS AND STRENGTHS

Injection: 160 mg/mL in a single-dose prefilled syringe or single-dose prefilled autoinjector. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Suicidal Ideation and Behavior (SI/B): May increase risk of SI/B. Advise patients, their caregivers, and families to monitor for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise them to promptly seek medical attention or call the National Suicide and Crisis Lifeline at 988. Carefully weigh risks and benefits of treatment with BIMZELX in patients with a history of severe depression and/or suicidal ideation or behavior. (5.1)
- Infections: May increase risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer BIMZELX until the infection resolves. (5.2)
- Tuberculosis (TB): Avoid use in patients with active TB. Initiate treatment of latent TB prior to BIMZELX treatment. (5.3)
- Liver Biochemical Abnormalities: Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management. Permanently discontinue use of BIMZELX in patients with causally - associated combined elevations of transaminases and bilirubin. (5.4)
- Inflammatory Bowel Disease (IBD): Cases of IBD were reported in clinical trials with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs. (5.5)

ADVERSE REACTIONS

Most common adverse reactions (\geq 1%) are upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes simplex infections, acne, folliculitis, other candida infections, and fatigue. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 844-599-2273 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Evaluations and Immunization Prior to Treatment Initiation

- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX [see *Warnings and Precautions (5.3)*].
- Test liver enzymes, alkaline phosphatase and bilirubin prior to initiating treatment with BIMZELX [see *Warnings and Precautions (5.4)*].
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines [see *Warning and Precautions (5.6)*].

2.2 Recommended Dosage

The recommended dosage of BIMZELX is 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider a dosage of 320 mg every 4 weeks after Week 16 [see *Clinical Pharmacology (12.3)*].

If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.

2.3 Preparation Instructions

- Before injecting, remove the carton with BIMZELX from the refrigerator and allow BIMZELX to reach room temperature (30 to 45 minutes) without removing the prefilled syringes or autoinjectors from the carton to protect from light.
- Inspect visually for particulate matter and discoloration prior to administration, whenever solution and container permit. BIMZELX injection is clear to slightly opalescent, and colorless to pale brownish- yellow. Do not use if the solution contains visible particles, is discolored or cloudy.

2.4 Administration Instructions

- BIMZELX is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in subcutaneous injection technique. Provide proper training to patients and/or caregivers on the subcutaneous injection technique of BIMZELX according to the "Instructions for Use" [see *Instructions for Use*].
- Each prefilled syringe or autoinjector of BIMZELX contains 160 mg of bimekizumab-bkzx. For each dose, inject two separate 160 mg single-dose prefilled syringes or autoinjectors subcutaneously at different anatomic locations (such as thighs, abdomen or back of upper arm). Discard the syringes or autoinjectors after use. Do not reuse.
- Do not inject BIMZELX within 2 inches (5 cm) of the navel or into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis. Administration of BIMZELX in the upper, outer arm may only be performed by a healthcare professional or caregiver.

3 DOSAGE FORMS AND STRENGTHS

Injection: 160 mg/mL clear to slightly opalescent, and colorless to pale brownish-yellow solution in a single-dose prefilled syringe or single-dose prefilled autoinjector.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Suicidal Ideation and Behavior

During the 16-week, placebo-controlled period of Trials Ps-1 and Ps-2, higher rates of suicidal ideation were reported in BIMZELX-treated subjects than in placebo-treated subjects.

Suicidal ideation and behavior were prospectively monitored using the Columbia Suicide Severity Rating Scale (C-SSRS) in clinical trials of psoriasis. The C-SSRS is an interview-based instrument used to monitor for the presence and severity of suicidal ideation (ranging from "none" to "active suicidal ideation with specific plan and intent") and behaviors (rating the injury and potential lethality of self-injury, if present). Pooled analysis of C-SSRS data from two 16-week, placebo-controlled clinical trials indicated that 12/670 (1.8%) BIMZELX-treated subjects and 1/169 (0.6%) placebo-treated subjects reported passive suicidal ideation with an estimated relative risk of 3.0 (95% confidence interval: 0.39, 22.74). Subjects without a prior history of SI/B treated with BIMZELX also reported a higher rate of new-onset suicidal ideation on the C-SSRS than subjects treated with placebo (1.3% vs. 0.6%). During the open-label extension trial, one completed suicide was reported in a BIMZELX-treated subject. [see *Adverse Reactions (6.1)*]. A causal association between treatment with BIMZELX and increased risk of suicidal ideation and behavior has not been established.

Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or suicidal ideation or behavior. Advise patients, their caregivers, and families to monitor for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise them to promptly seek medical attention or call the National Suicide and Crisis Lifeline at 988 [see *Patient Counseling Information (17)*]. BIMZELX-treated patients with new or worsening symptoms of depression or suicidal ideation and/or behavior should be referred to a mental health professional, as appropriate. Prescribers should also re-evaluate the risks and benefits of continuing treatment with BIMZELX if such events occur.

5.2 Infections

BIMZELX may increase the risk of infections. In clinical trials in subjects with plaque psoriasis, infections occurred in 36% of the BIMZELX group compared to 23% of the placebo group through 16 weeks of treatment. Upper respiratory tract infections, Candida infections, tinea infections, gastroenteritis, and Herpes Simplex infections occurred more frequently in the BIMZELX group than in the placebo group [see *Adverse Reactions (6.1)*].

Serious infections occurred in 0.3% of subjects treated with BIMZELX and 0% treated with placebo.

Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and discontinue BIMZELX until the infection resolves.

5.3 Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients treated with BIMZELX for signs and symptoms of active TB during and after treatment.

5.4 Liver Biochemical Abnormalities

Treatment with BIMZELX was associated with increased incidence of liver enzyme elevations compared to treatment with placebo in randomized clinical trials. Liver serum transaminase elevations > 3 times the upper limit of normal were reported in subjects treated with BIMZELX [see *Adverse Reactions (6.1)*]. Elevated liver serum transaminases resolved after discontinuation of BIMZELX. The time to onset of these adverse reactions varied between 28 and 198 days after starting BIMZELX treatment.

Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Patients with acute liver disease or cirrhosis may be at increased risk for severe hepatic injury; avoid use of BIMZELX in these patients.

5.5 Inflammatory Bowel Disease

Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX [see *Adverse Reactions (6.1)*]. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

5.6 Immunizations

Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX. Limited data are available regarding coadministration of BIMZELX with non-live vaccines [see *Clinical Pharmacology (12.2)*].

6 ADVERSE REACTIONS

The following adverse reactions have been observed with BIMZELX and are discussed in greater detail in other sections of the labeling:

- Suicidal Ideation and Behavior [see *Warnings and Precautions (5.1)*]

- Infections [see Warnings and Precautions (5.2)]
- Liver Biochemical Abnormalities [see Warnings and Precautions (5.4)]
- Inflammatory Bowel Disease [see Warnings and Precautions (5.5)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, a total of 1789 subjects with plaque psoriasis were treated with BIMZELX. Of these, 1073 subjects were exposed to BIMZELX for at least one year.

The safety of BIMZELX was evaluated in two placebo-controlled trials (Ps-1 and Ps-2), an active-controlled trial (Ps-3), and an open-label extension trial. Data from Trials Ps-1 and Ps-2 in 839 subjects (mean age 45 years, 72% male, 84% white) were pooled to evaluate the safety of BIMZELX in comparison to placebo up to 16 weeks after treatment initiation. A total of 670 subjects were treated during this initial period with BIMZELX 320 mg at Weeks 0, 4, 8, 12, and 16. Table 1 summarizes the adverse reactions that occurred at a rate of 1% or greater and at a higher rate in the BIMZELX group than the placebo group.

Table 1: Adverse Reactions Occurring in $\geq 1\%$ of Subjects with Plaque Psoriasis in the BIMZELX Group and More Frequently than in the Placebo Group in Trials Ps-1 and Ps-2

	BIMZELX N=670 n (%)	Placebo N=169 n (%)
URI*	102 (15)	24 (14)
Oral Candidiasis†	61 (9)	0 (0)
Headache	22 (3)	0 (0)
Injection Site Reactions‡	19 (3)	2 (1)
Tinea Infections§	18 (3)	1 (1)
Gastroenteritis¶	12 (2)	0 (0)
Herpes Simplex Infections#	9 (1)	0 (0)
Acne	8 (1)	0 (0)
Folliculitis	8 (1)	0 (0)
Other Candida Infections ^P	7 (1)	1 (1)
Fatigue	7 (1)	0 (0)

* Upper Respiratory Infections include nasopharyngitis, upper respiratory tract infection, pharyngitis, rhinitis, viral upper respiratory tract infection, tonsillitis, sinusitis, pharyngitis streptococcal, pharyngitis bacterial, peritonsillar abscess, viral rhinitis, and influenza

† Oral Candidiasis includes oral candidiasis, oropharyngeal candidiasis, oral fungal infection, fungal pharyngitis, and oropharyngitis fungal

‡ Injection Site Reactions include injection site reaction, injection site erythema, injection site pain, injection site edema, injection site bruising, and injection site swelling

§ Tinea Infections include tinea pedis, fungal skin infection, tinea versicolor, tinea cruris, tinea infection, body tinea, and onychomycosis

- ¶ Gastroenteritis includes Enterovirus infection, gastroenteritis, gastroenteritis bacterial, and gastroenteritis viral
- # Herpes Simplex Infections include herpes simplex and oral herpes
- ¶ Other Candida Infections include vulvovaginal candidiasis, vulvovaginal mycotic infection, skin candida, and genital candidiasis.

Adverse reactions that occurred in < 1% but > 0.1% of subjects in the BIMZELX group and at a higher rate than in the placebo group through Week 16 were neutropenia, eczema, otitis externa, otitis media, and pyrexia.

The safety of BIMZELX was evaluated in another active-controlled trial (Ps-4) in 743 adult subjects who received BIMZELX 320 mg every 4 weeks or every 8 weeks through Week 48.

Specific Adverse Reactions

Suicidal Ideation and Behavior: The study populations of Trial Ps-1, Trial Ps-2, Trial Ps-3 and Trial Ps-4 excluded subjects with active suicidal ideation, suicidal ideation within the month prior to screening, a history of suicide attempt within the past 5 years prior to screening, or moderately severe to severe major depression (i.e., score of ≥ 15 on the screening Patient Health Questionnaire-9 (PHQ-9)).

Based on a pooled analysis of the first 16 weeks of the placebo controlled clinical trials, 12 of the 670 subjects in the BIMZELX group (1.8%) reported passive suicidal ideation on the C-SSRS compared to 1 of 169 subjects in the placebo group (0.6%).

During the course of the clinical trials for plaque psoriasis, there was 1 completed suicide in the open label extension trial after 718 days of treatment (1/2480; 0.01/100 subject-years). The completed suicide was reported in a subject without a past reported psychiatric history. There were also 3 suicide attempts (3/2480; 0.04/100 subject-years); 2 of these subjects had a history of prior suicide attempts.

Infections: During the placebo-controlled period of Trials Ps-1 and Ps-2, infections were reported in 36% of subjects (141.7 per 100 patient-years) treated with BIMZELX compared with 23% of subjects (84.6 per 100 patient-years) treated with placebo. Serious infections occurred in 0.3% of subjects (1.0 per 100 patient-years) treated with BIMZELX and 0% treated with placebo.

The most common infections were upper respiratory tract infections and Candida infections, including oral candidiasis (oral candidiasis, oropharyngeal candidiasis, oral fungal infection, fungal pharyngitis, and oropharyngitis fungal) occurring in 9% (30.6 per 100 patient-years) of subjects treated with BIMZELX and other Candida infections (vulvovaginal candidiasis, vulvovaginal mycotic infection, skin candida, and genital candidiasis) in 1% (3.4 per 100 patient-years) of subjects treated with BIMZELX compared to 0% and 1%, respectively, of subjects treated with placebo.

During the combined initial, maintenance, and open-label extension treatment periods of trials Ps-1, Ps-2, Ps-3, and the open-label extension trial, infections were reported in 63% of subjects treated with BIMZELX (120.4 per 100 patient-years). Serious infections were reported in 1.5% of subjects treated with BIMZELX (1.6 per 100 patient-years).

Inflammatory Bowel Disease: In clinical trials in subjects with plaque psoriasis, subjects with active inflammatory bowel disease were excluded. In these trials, which included 2480 subjects exposed to BIMZELX accounting for 5830 patient-years, adjudicated cases of new onset of inflammatory bowel disease (including ulcerative colitis (UC),

Crohn's disease (CD) and IBD-undetermined) occurred in seven subjects (0.12 per 100 patient-years); the majority of these cases were serious and resulted in discontinuation of therapy. In clinical development programs for other disease conditions, new cases of Crohn's disease (CD) and UC, some serious, and exacerbations of pre-existing CD and UC, were reported with BIMZELX use.

Liver Biochemical Abnormalities: During the placebo-controlled period of Trials Ps-1 and Ps-2, liver serum transaminase elevations (> 3 times the upper limit of normal [ULN]) occurred in 1.0% of subjects treated with BIMZELX versus 0.6% of subjects treated with placebo. Elevated liver serum transaminases resolved during continued treatment or after discontinuation of BIMZELX.

Safety through Week 56

During the maintenance period (Week 16 through Week 52 of Trial Ps-1 and Week 56 of Trial Ps-2), no new adverse reactions were identified after the initial 16 weeks of treatment. During the maintenance treatment periods of Trial Ps-2 and Trial Ps-3, the rates of adverse reactions were similar between subjects treated with BIMZELX 320 mg every four weeks and every eight weeks, after the initial 16 weeks of treatment.

Safety through Week 128

During the open-label extension trial, including data from Week 56 through Week 128, new adverse reactions of suicide attempt and a completed suicide occurred.

Additional Safety Data

In an active-controlled clinical trial (Trial Ps-4), 691 subjects with plaque psoriasis were treated with bimekizumab for up to 144 weeks. No new adverse reactions were identified.

7 DRUG INTERACTIONS

CYP450 Substrates

The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNF α , IFN) during chronic inflammation. Treatment with BIMZELX may modulate serum levels of some cytokines.

Therefore, upon initiation or discontinuation of BIMZELX in patients who are receiving concomitant drugs which are CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) and consider dosage modification of the CYP450 substrate.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to BIMZELX during pregnancy. For more information, healthcare providers or patients can contact the Organization of Teratology Information Specialists (OTIS)

AutoImmune Diseases Study at 1-877-311-8972 or visit <http://mothertobaby.org/pregnancy-studies/>.

Risk Summary

Available data from case reports on BIMZELX use in pregnant women are insufficient to evaluate for a drug associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Transport of human IgG antibody across the placenta increases as pregnancy progresses and peaks during the third trimester; therefore, BIMZELX may be transmitted from the mother to the developing fetus (*see Clinical Considerations*). In an enhanced pre- and postnatal development study, no adverse developmental effects were observed in infants born to pregnant monkeys after subcutaneous administration of bimekizumab-bkzx during the period of organogenesis through parturition at doses up to 38 times the maximum recommended human dose (MRHD) (*see Data*).

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions: Because bimekizumab-bkzx may interfere with immune response to infections, risks and benefits should be considered prior to administering live vaccines to infants exposed to BIMZELX in utero. There are no data regarding infant serum levels of bimekizumab-bkzx at birth and the duration of persistence of bimekizumab-bkzx in infant serum after birth. Although a specific timeframe to delay live virus immunizations in infants exposed in utero is unknown, a minimum of 4 months after birth may be considered because of the half-life of the product.

Data

Animal Data: An enhanced pre- and postnatal developmental toxicity study was conducted in cynomolgus monkeys. Pregnant cynomolgus monkeys were administered subcutaneous doses of bimekizumab-bkzx of 20 or 50 mg/kg/week from gestation day 20 to parturition and the cynomolgus monkeys (mother and infants) were monitored for 6 months after delivery. No maternal toxicity was noted in this study. There were no treatment-related effects on growth and development, malformations, developmental immunotoxicology or neurobehavioral development. The no observed adverse effect level (NOAEL) for both maternal and developmental toxicity was identified as 50 mg/kg/week (38 times the MRHD, based on mg/kg comparison of 1.33 mg/kg/week administered as a 320 mg dose to a 60 kg individual once every 4 weeks).

8.2 Lactation

Risk Summary

There are no data on the presence of bimekizumab-bkzx in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Endogenous IgG and monoclonal antibodies are transferred in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to bimekizumab-bkzx

are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BIMZELX and any potential adverse effects on the breastfed infant from BIMZELX or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of BIMZELX in pediatric patients have not been established.

8.5 Geriatric Use

Of the 1789 subjects with plaque psoriasis that were exposed to BIMZELX, a total of 153 subjects were 65 years of age or older, and 18 subjects were 75 years of age or older. Although no differences in safety or effectiveness were observed between subjects 65 years of age or older and younger adult subjects, the number of subjects aged 65 years and over is not sufficient to determine whether they respond differently from younger adult subjects.

11 DESCRIPTION

Bimekizumab-bkzx, an interleukin-17 A and F antagonist, is a recombinant humanized immunoglobulin G1 (IgG1) monoclonal antibody. Bimekizumab-bkzx is produced by recombinant DNA technology in Chinese Hamster Ovary cells, and has an approximate molecular weight of 150 kDa.

BIMZELX (bimekizumab-bkzx) injection is a sterile, preservative-free, clear to slightly opalescent, and colorless to pale brownish-yellow solution for subcutaneous use.

Each BIMZELX prefilled syringe or prefilled autoinjector delivers 1 mL containing 160 mg bimekizumab-bkzx, glacial acetic acid (1.23 mg), glycine (16.5 mg), polysorbate 80 (0.4 mg), sodium acetate (2.83 mg), and Water for Injection, USP at pH 5.1.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bimekizumab-bkzx is a humanized immunoglobulin IgG1/ κ monoclonal antibody with two identical antigen binding regions that selectively bind to human interleukin 17A (IL-17A), interleukin 17F (IL-17F), and interleukin 17-AF cytokines, and inhibits their interaction with the IL-17receptor complex. IL-17A and IL-17F are naturally occurring cytokines that are involved in normal inflammatory and immune responses. Bimekizumab-bkzx inhibits the release of proinflammatory cytokines and chemokines.

12.2 Pharmacodynamics

Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin. Bimekizumab-bkzx exposure-response relationships to serum biomarkers, including IL-17A and IL-17F, and the time course of such pharmacodynamic responses are unknown.

Immune Response to Inactivated or Non-Live Vaccines

Healthy individuals who received a single 320 mg dose of BIMZELX two weeks prior to vaccination with an inactivated seasonal influenza vaccine had similar antibody

responses compared to individuals who did not receive BIMZELX prior to vaccination. The effectiveness of inactivated seasonal influenza vaccines and other inactivated and non-live vaccines has not been evaluated in patients treated with BIMZELX.

12.3 Pharmacokinetics

The following pharmacokinetic parameters are reported for adult patients with moderate to severe plaque psoriasis, unless otherwise specified. The median peak plasma concentration of bimekizumab-bkzx was 25 (range: 12-50) µg/mL and was reached in 3-4 days. Bimekizumab-bkzx exhibited dose-proportional pharmacokinetics in patients with plaque psoriasis over a dose range of 64 mg to 480 mg (0.2 to 1.5 times the approved recommended dosage) following subcutaneous administration.

Absorption

The absolute bioavailability of bimekizumab-bkzx was 70% in healthy subjects.

Distribution

The median volume of distribution at steady state was 11.2 L.

Elimination

The median (coefficient of variation %) clearance (CL/F) of bimekizumab-bkzx was 0.337 L/day (32.7%). The mean terminal elimination half-life was 23 days, with clearance independent of dose.

Metabolism: Bimekizumab-bkzx is expected to be degraded into small peptides by catabolic pathways.

Specific Populations

No significant differences in the pharmacokinetics of bimekizumab-bkzx were observed based on age (≥ 18 years).

Body Weight: The average plasma concentration in adult subjects weighing ≥ 120 kg was predicted to be at least 30% lower than those weighing < 120 kg (median of 87 kg) [see *Dosage and Administration Section (2.2)*].

12.6 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADA in the studies described below with the incidence of ADA in other studies, including those of BIMZELX or of other bimekizumab products.

During the 52–56-week treatment period in Trial-Ps-1, Trial-Ps-2, and Trial-Ps-3 [see *Clinical Studies (14)*], 116/257 (45%) of BIMZELX-treated subjects (at the recommended dosage) developed anti-bimekizumab-bkzx antibodies (also referred to as ADA). Of the BIMZELX-treated subjects who developed ADA in these trials, approximately 16% had neutralizing antibodies. There was no identified clinically significant effect of ADA on safety or effectiveness of BIMZELX over the treatment duration of 56 weeks.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity and mutagenicity studies have not been conducted with bimekizumab-bkzx.

No effects on fertility parameters such as effects on reproductive organs, menstrual cycle length, or sperm analysis were observed in sexually mature cynomolgus monkeys that were subcutaneously administered 200 mg/kg/week bimekizumab-bkzx (150 times the MRHD, based on mg/kg comparison) for 26 weeks. The monkeys were not mated to evaluate fertility.

14 CLINICAL STUDIES

Three multicenter, randomized, double-blind trials [Trial-Ps-1 (NCT03370133), Trial-Ps-2 (NCT03410992), and Trial-Ps-3 (NCT03412747)] enrolled a total of 1480 subjects 18 years of age and older with moderate to severe plaque psoriasis who had a body surface area (BSA) involvement of $\geq 10\%$, an Investigator's Global Assessment (IGA) score of ≥ 3 ("moderate") in the overall assessment of psoriasis on a severity scale of 0 to 4, and a Psoriasis Area and Severity Index (PASI) score ≥ 12 .

In Trial-Ps-1, 567 subjects were randomized to receive either BIMZELX 320 mg by subcutaneous injection every 4 weeks, ustekinumab (for subjects weighing ≤ 100 kg, 45 mg initially and 4 weeks later, then every 12 weeks; for subjects weighing >100 kg, 90 mg initially and 4 weeks later, then every 12 weeks), or placebo through Week 52. At Week 16, subjects originally randomized to placebo received BIMZELX 320 mg every 4 weeks through Week 52.

In Trial-Ps-2, 435 subjects were randomized to either BIMZELX 320 mg by subcutaneous injection every 4 weeks or placebo. At Week 16, subjects who achieved a PASI 90 response continued into a 40-week randomized withdrawal period. Subjects originally randomized to BIMZELX 320 mg every 4 weeks were re-randomized to either BIMZELX 320 mg every 4 weeks or BIMZELX 320 mg every 8 weeks or placebo. Subjects originally randomized to placebo continued to receive placebo if they were PASI 90 responders. Subjects who did not achieve a PASI 90 response at week 16 entered an open-label escape arm and received BIMZELX 320 mg every 4 weeks for 12 weeks. Subjects who relapsed, defined as having a less than PASI 75 response compared to baseline, during the randomized withdrawal period also entered the 12-week escape arm.

In Trial-Ps-3, 478 subjects were randomized to receive either BIMZELX 320 mg by subcutaneous injection every 4 weeks through week 56, BIMZELX 320 mg every 4 weeks through week 16 followed by BIMZELX every 8 weeks through week 56, or adalimumab (80 mg as an initial dose followed by 40 mg every other week starting 1 week after initial dose through Week 24) followed by BIMZELX 320 mg every 4 weeks through Week 56.

In Trial-Ps1, Trial-Ps-2, and Trial-Ps-3, 71% of the subjects were male and 84% of the subjects were White, with a mean age of 45 years and a mean weight of 89 kg. At baseline, subjects had a median baseline PASI score of 18, median baseline for BSA of 20%, and baseline IGA score of 4 ("severe") in 33% of subjects. A total of 93% subjects had psoriasis of the scalp (Scalp IGA score of ≥ 1) and a total of 26% of subjects had a history of psoriatic arthritis. Additionally, 38% had received prior biologic therapy.

Clinical Response at Week 16 (Trial-Ps-1 and Trial-Ps-2)

Trial-Ps-1 and Trial-Ps-2 responses at Week 16 compared to placebo for the two co-primary endpoints:

- The proportion of subjects who achieved an IGA score of 0 ("clear") or 1 ("almost clear") with at least a 2-grade improvement from baseline
- The proportion of subjects who achieved at least a 90% reduction from baseline PASI (PASI 90)

Secondary endpoints included the proportion of subjects who achieved PASI 100, IGA 0, and Scalp IGA response (defined as Scalp IGA score of 0 [clear] or 1 [almost clear] with at least 2-grade of improvement from baseline) at Week 16, and PASI 75 at Week 4. In addition, secondary endpoints included assessment of psoriasis symptoms (itching, pain, and scaling) measured by the Patient Symptom Diary (PSD) at Week 16.

The proportion of subjects who achieved IGA 0 or 1, PASI 90, IGA 0, and PASI 100 response at Week 16 are presented in Table 2.

Table 2: Efficacy Results at Week 16 in BIMZELX- or Placebo-Treated Adults with Plaque Psoriasis in Trial-Ps-1 and Trial-Ps-2

	Trial-Ps-1		Trial-Ps-2	
	BIMZELX 320 mg every 4 weeks (N=321) n (%)	Placebo (N=83) n (%)	BIMZELX 320 mg every 4 weeks (N=349) n (%)	Placebo (N=86) n (%)
IGA 0 or 1 ("clear" or "almost clear") *	270 (84%)	4 (5%)	323 (93%)	1 (1%)
<i>Difference (95% CI)</i>	79% (73%, 85%)		91% (88%, 95%)	
PASI 90*	273 (85%)	4 (5%)	317 (91%)	1 (1%)
<i>Difference (95% CI)</i>	80% (74%, 86%)		90% (86%, 93%)	
IGA 0 ("clear")	188 (59%)	0 (0%)	243 (70%)	1 (1%)
<i>Difference (95% CI)</i>	59% (53%, 64%)		69% (64%, 74%)	
PASI 100	188 (59%)	0 (0%)	238 (68%)	1 (1%)
<i>Difference (95% CI)</i>	59% (53%, 64%)		67% (62%, 73%)	

* Co-primary endpoints

Examination of age, gender, race, baseline IGA score and previous treatment with systemic or biologic agents did not identify differences in response to BIMZELX among these subgroups at Week 16.

A greater proportion of subjects randomized to BIMZELX achieved PASI 75 at Week 4 in both trials compared to placebo. In Trial-Ps-1, 77% of subjects treated with BIMZELX achieved PASI 75 compared to 2% treated with placebo. In Trial-Ps-2, 76% of subjects treated with BIMZELX achieved PASI 75 compared to 1% treated with placebo.

Among subjects with Scalp IGA score of at least 2 at baseline, a greater proportion of subjects randomized to BIMZELX achieved Scalp IGA response at Week 16 in both trials compared to placebo. In Trial-Ps-1, 84% (240/285) of subjects treated with BIMZELX

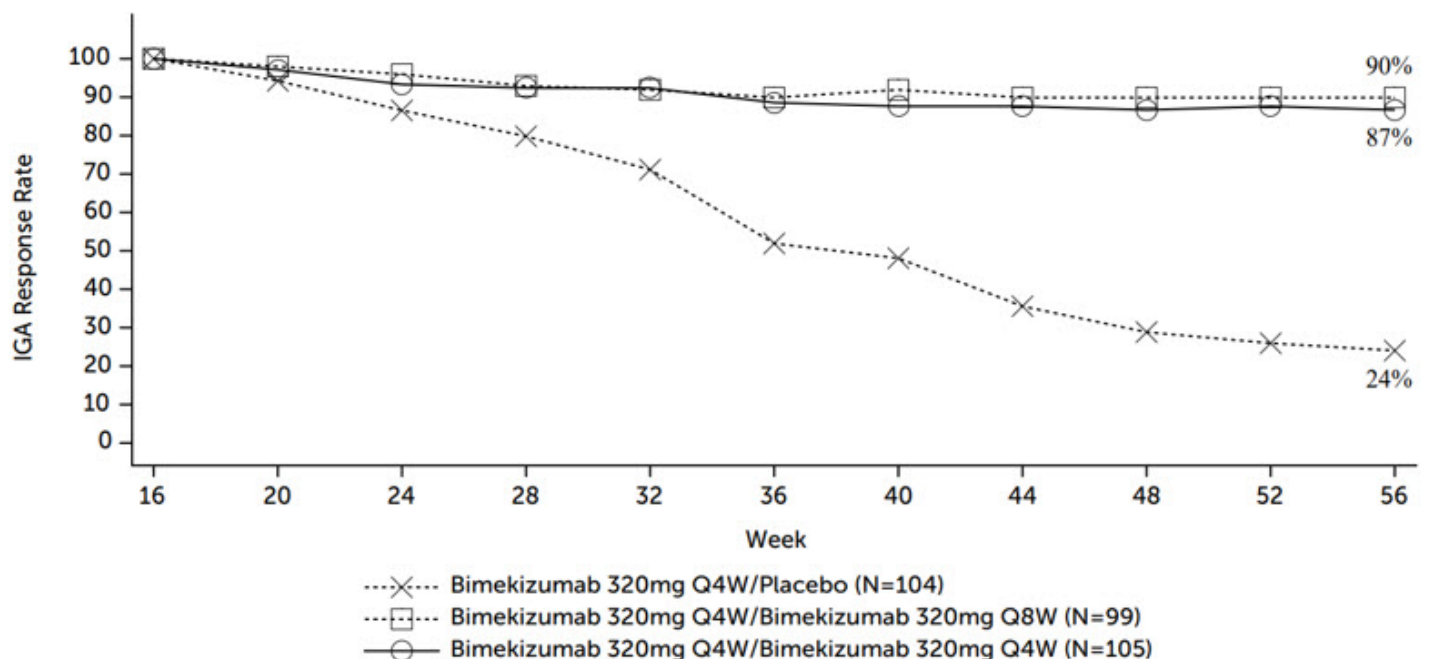
achieved Scalp IGA response compared to 15% (11/72) of placebo treated subjects. In Trial-Ps-2, 92% (286/310) of subjects treated with BIMZELX achieved Scalp IGA response compared to 7% (5/74) of placebo treated subjects.

Maintenance and Durability of Response

In Trial-Ps-2, subjects randomized to BIMZELX every 4 weeks at Week 0 and who were PASI 90 responders at Week 16 were re-randomized to either continue treatment with BIMZELX every 4 weeks, switched to BIMZELX every 8 weeks, or be withdrawn from therapy (i.e., received placebo).

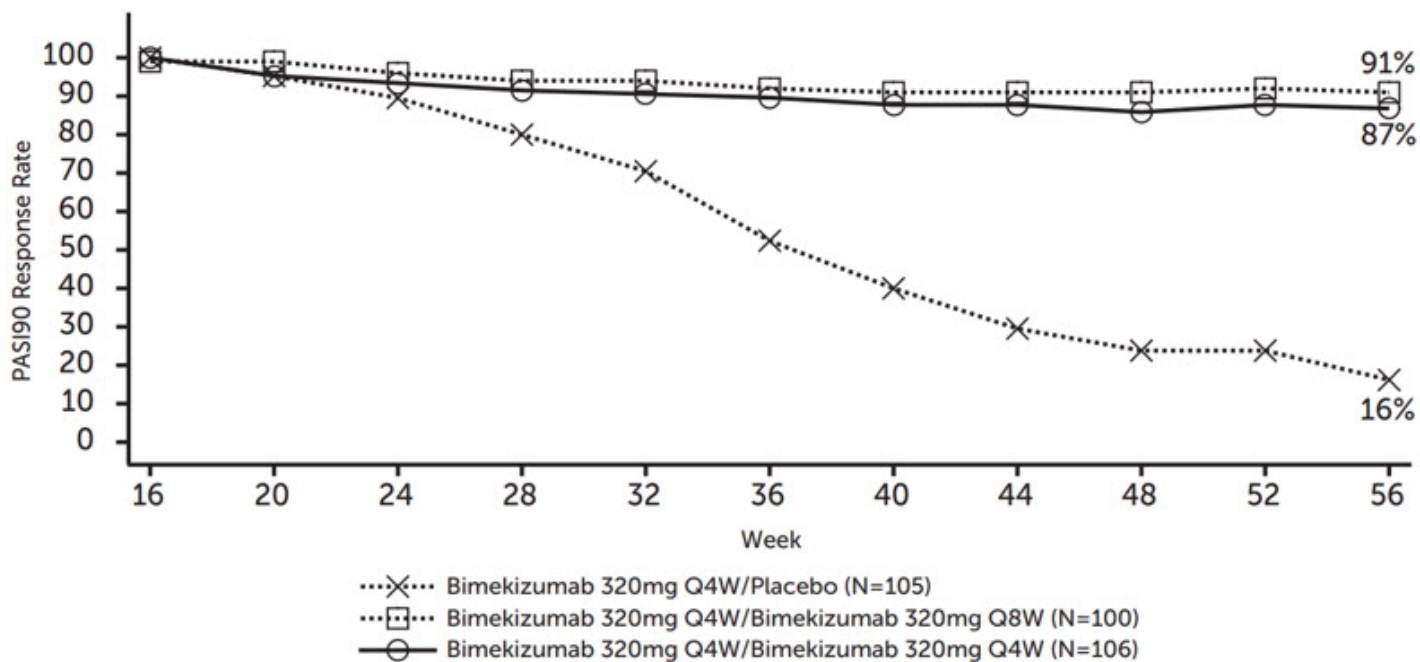
Figure 1 and Figure 2 present the percentage of subjects maintaining IGA score of 0 ("Clear") or 1 ("Almost Clear") and PASI 90, respectively, through Week 56 after re-randomization at Week 16.

Figure 1: Percentage of Subjects Maintaining IGA 0 or 1 through Week 56 after Re-Randomization at Week 16



For IGA 0 or 1 responders at Week 16 who were re-randomized to treatment withdrawal (i.e., placebo), the median time to loss of IGA 0 or 1 response was approximately 24 weeks. Among these subjects with IGA score of 2 at retreatment, 58% (14/24) achieved IGA score of 0 within 12 weeks of restarting treatment with BIMZELX 320 mg every 4 weeks. Among these subjects with IGA score ≥ 3 at retreatment, 87% (34/39) regained IGA 0 or 1 response with at least 2-grade improvement from retreatment within 12 weeks of restarting treatment with BIMZELX 320 mg every 4 weeks.

Figure 2: Percentage of Subjects Maintaining PASI 90 through Week 56 after Re-Randomization at Week 16



For PASI 90 responders at Week 16 who were re-randomized to treatment withdrawal (i.e., placebo), the median time to loss of PASI 90 response was approximately 24 weeks.

Patient Reported Outcomes

Greater improvements in itch, pain, and scaling at Week 16 with BIMZELX compared to placebo were observed in both trials as measured by the Patient Symptom Diary (PSD).

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

BIMZELX (bimekizumab-bkzx) injection is a sterile, preservative-free, clear to slightly opalescent, and colorless to pale brownish-yellow solution. Each prefilled autoinjector or prefilled syringe contains 1 mL of a 160mg/mL solution. BIMZELX is supplied as:

BIMZELX autoinjector:

- NDC 50474-781-85: Carton of two 160 mg/mL single-dose autoinjectors. Each prefilled autoinjector is fixed with a 27 gauge ½ inch needle.

BIMZELX prefilled syringe:

- NDC 50474-780-79: Carton of two 160 mg/mL single-dose prefilled syringes. Each prefilled syringe is fixed with a 27 gauge ½ inch needle with needle guard.

Storage and Handling

Store cartons with BIMZELX refrigerated between 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect it from light until the time of use. Do not freeze. Do not shake. Do not use beyond expiration date. BIMZELX does not contain a preservative; discard any unused portion. Not made with natural rubber latex.

When necessary, BIMZELX prefilled syringes or autoinjectors may be stored at room temperature up to 25°C (77°F) in the original carton for a single period of up to 30 days.

Once BIMZELX prefilled syringes or autoinjectors have been stored at room temperature, do not place back in refrigerator. Write the date removed from the refrigerator in the space provided on the carton and discard if not used within a 30-day period.

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Administration Instructions

Instruct patients or caregivers to perform the first self-injection under the supervision and guidance of a qualified healthcare professional for proper training in subcutaneous injection technique [see *Dosage and Administration (2.4), Instructions for Use*].

Instruct patients or caregivers to administer two 160 mg single-dose syringes or two 160 mg single-dose autoinjectors to achieve the 320 mg dose of BIMZELX [see *Dosage and Administration (2.4)*].

Instruct patients or caregivers in the technique of needle and syringe disposal [see *Instructions for Use*].

Advise patients if they forget to take their dose of BIMZELX to inject their dose as soon as they remember. Instruct patients to then take their next dose at the appropriate scheduled time [see *Dosage and Administration (2.2)*].

Suicidal Ideation and Behavior

Instruct patients and their caregivers to monitor for the emergence of suicidal ideation and behavior and promptly seek medical attention if the patient experiences suicidal ideation or behavior; or new onset or worsening depression, anxiety, or other mood changes. Instruct patients to call the National Suicide and Crisis Lifeline at 988 if they experience suicidal ideation or behavior. [see *Warnings and Precautions (5.1)*].

Infections

Inform patients that BIMZELX may lower the ability of their immune system to fight infections. Instruct patients of the importance of communicating any history of infections to the healthcare provider and contacting their healthcare provider if they develop any symptoms of an infection [see *Warnings and Precautions (5.2)*].

Liver Biochemical Abnormalities

Inform patients that BIMZELX may increase the risk of elevated liver enzymes. Acute liver disease or cirrhosis may increase this risk. Advise patients that laboratory evaluation is needed prior to and periodically during treatment. Advise patients to hold the next dose of BIMZELX and call their healthcare provider right away, if signs or symptoms of liver dysfunction occur. [see *Warnings and Precautions (5.4)*].

Inflammatory Bowel Disease

Instruct patients to seek medical advice if they develop signs and symptoms of Crohn's disease or ulcerative colitis [see *Warnings and Precautions (5.5)*].

Immunizations

Advise patients that vaccination with live vaccines is not recommended during BIMZELX treatment. Instruct patients to inform their healthcare practitioner that they are taking BIMZELX prior to a potential vaccination [see *Warnings and Precautions (5.6)*].

Pregnancy

Advise patients that there is a pregnancy registry that monitors pregnancy outcomes in women exposed to BIMZELX during pregnancy [see *Use in Specific Populations (8.1)*].

Manufactured by:

UCB, Inc.

1950 Lake Park Drive Smyrna, GA 30080

US License No. 1736

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 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.
 - 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
 - weight loss
 - warm, red, or painful skin or sores on your body different from your psoriasis

- cough
- shortness of breath
- blood in your phlegm
- 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). 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 include:

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

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.

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1950 Lake Park Drive Smyrna, GA 30080

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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.

Issued: 10/2023

INSTRUCTIONS for USE

BIMZELX[®] (bim zel' ex)

(bimekizumab-bkzx)

injection, for subcutaneous use

single-dose autoinjector

This Instructions for Use contains information on how to inject BIMZELX.

Read this Instructions for Use before using the BIMZELX autoinjector and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

For a full dose, 2 injections are required, one after the other. Each BIMZELX autoinjector is for one-time (single-dose) use only.

Important Information you Need to Know Before Injecting BIMZELX:

- Your healthcare provider should show you or a caregiver how to prepare and inject BIMZELX using the autoinjector for the first time. Do not inject yourself or someone else until you have been shown how to inject BIMZELX the right way. Call your healthcare provider if you have any questions.
- These instructions are for 1 injection only. **For a full dose, 2 injections are required, one after the other.**
- The BIMZELX autoinjector has a needle safety feature that will be activated to cover the needle after the injection is finished. The needle safety feature will help to prevent needle stick injuries to anyone who handles the autoinjector after injection.
- **Do not** share or reuse your BIMZELX autoinjector. You may give or get an infection.
- **Do not** remove the needle cap until just before you give the injection.
- If you have vision or hearing problems, **do not** use the BIMZELX autoinjector without help from a caregiver.

How should I store BIMZELX autoinjector?

- Store the BIMZELX autoinjector in the refrigerator between 36°F to 46°F (2°C to

8°C).

- BIMZELX autoinjectors may be stored at room temperature up to 77°F (25°C) in the original carton for up to 30 days. **Do not** place BIMZELX 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 if it has been kept at room temperature and not 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 the BIMZELX autoinjector past the expiration date printed on the carton.

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

BIMZELX autoinjector parts (see Figure A):

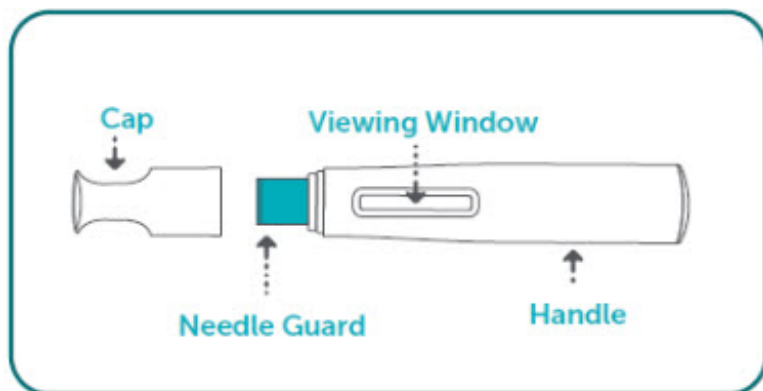


Figure A

Supplies Needed for each BIMZELX injection

- 1 BIMZELX autoinjector

Not provided in the BIMZELX autoinjector carton:

- 1 alcohol swab
- 1 clean cotton ball
- 1 sharps disposal container. See, "**Step 12: Dispose of (throw away) the used BIMZELX autoinjector**" at the end of this Instructions for Use.

Setting up for your BIMZELX injection.

Step 1: Take the BIMZELX autoinjector carton out of the refrigerator. Do not use the BIMZELX autoinjector(s) if the carton seal is broken. Throw it away and get a new one.

- **Keep the BIMZELX autoinjector in its original carton for 30 to 45 minutes** to warm to room temperature. This will help to reduce discomfort when injecting.
 - **Do not** microwave the autoinjector, run hot water over it, or leave it in direct sunlight.
 - **Do not** shake the autoinjector.
 - **Do not** take the cap off the autoinjector until you are ready to inject.

Step 2: Find a clean, flat, and well-lit work surface, like a table.

Step 3: Gather the supplies needed for your injection.

Step 4: Wash your hands well with soap and water and dry with a clean towel.

Step 5: Inspect the BIMZELX autoinjector (**see Figure B**):

- Remove the BIMZELX autoinjector from the carton.
- **Make sure the name BIMZELX appears on the label.**
 - Check the expiration date printed on the label.
 - Check the medicine through the Viewing Window. The medicine inside should be clear to slightly pearly, and colorless to pale brownish-yellow. You may see air bubble(s) in the liquid. This is normal.
- **Do not use the BIMZELX autoinjector**, throw it away and get a new one if:
 - The expiration date printed on the label has passed.
 - The medicine is cloudy, discolored, or has particles.
 - It looks damaged or has been dropped.

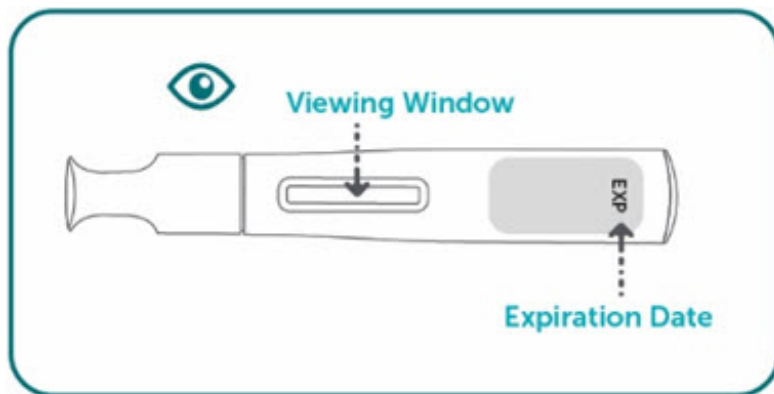
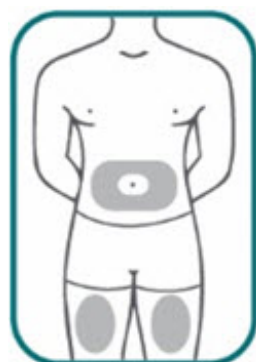


Figure B

Choose and prepare your injection site.

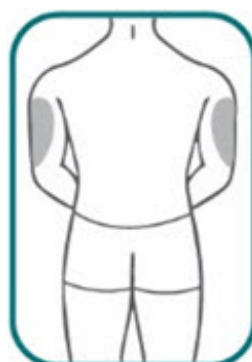
Step 6: Choose and clean your injection site.

- **The sites you may choose for your injection are:**
 - your stomach area (abdomen) or your thigh (**see Figure C**).
 - the back of your arm (**see Figure D**). BIMZELX may be injected into the back of your arm by a healthcare provider or caregiver only.



Abdomen or
thigh

Figure C



Back of arm

Figure D

- **Do not** inject into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis, or within 2 inches of the belly button (navel).

- Choose a different site for each injection. **Do not** use the same injection site 2 times in a row.

Step 7: Prepare your skin

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

Injecting BIMZELX.

Step 8: Remove the BIMZELX autoinjector cap.

- Hold the BIMZELX autoinjector firmly with one hand around the handle. Pull the cap straight off (away from) the autoinjector with the other hand (**see Figure E**). Although you cannot see the needle tip, it is now uncovered.
 - **Put** the cap into an FDA-cleared sharps disposal container right away. You will not need it again.
 - **Do not** touch the needle guard or put the cap back on as it could activate the autoinjector and you can stick yourself.

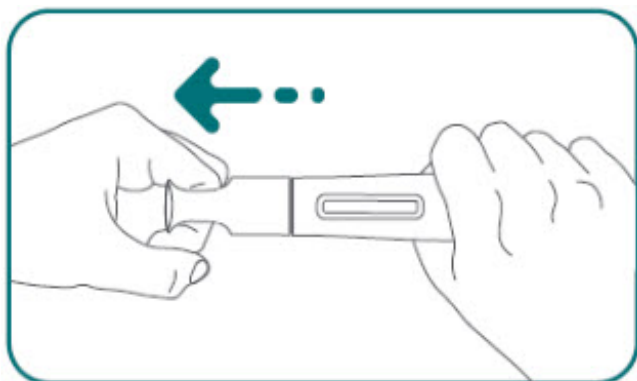


Figure E

Step 9: Hold the BIMZELX autoinjector at a 90-degree angle to the cleaned injection site (**see Figure F**).

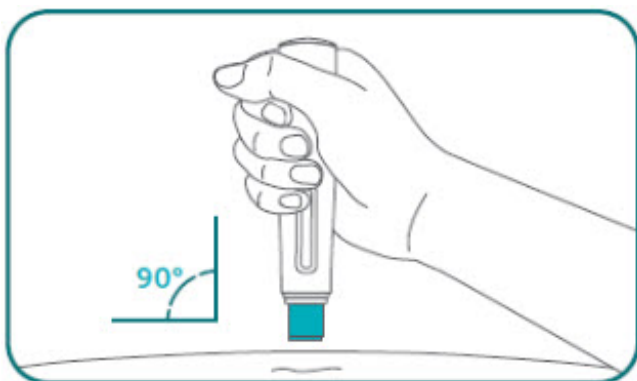


Figure F

Step 10: Place the BIMZELX autoinjector flat against your skin, then firmly press the BIMZELX autoinjector down against your skin. **You will hear a "click" sound.** Your injection begins when the 1st "click" is heard (**see Figure G**).

- **Do not** lift the autoinjector away from the skin.

Keep holding the BIMZELX autoinjector in place and pressed firmly against your skin. It will take about 15 seconds to receive your full dose.

- You will hear a 2nd "click" in about 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 color indicator filling the viewing window (**see Figure H**).
- **Important:** When you remove the autoinjector, if the window has not turned yellow this means you may not have received a full dose. Call your healthcare provider right away.

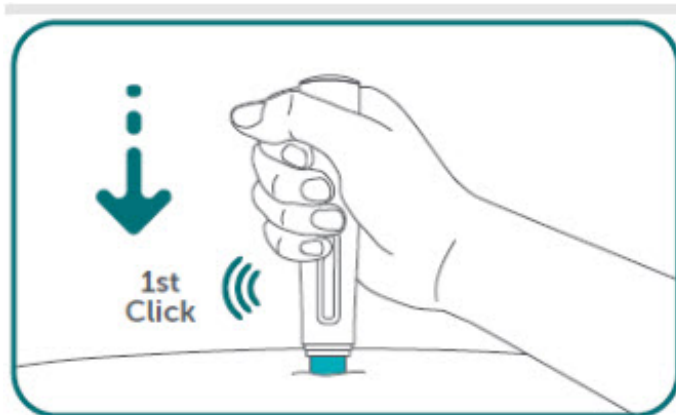


Figure G

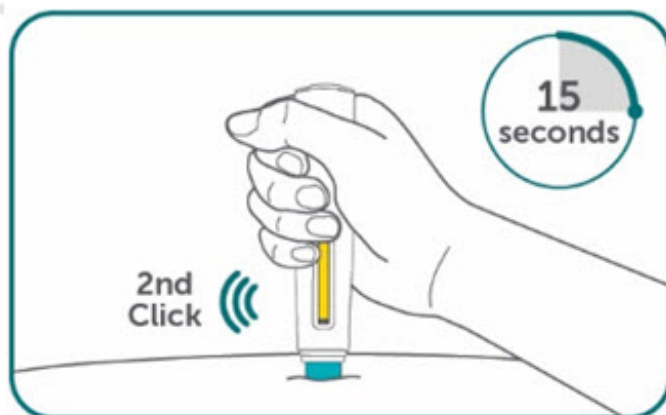


Figure H

Step 11: Remove the BIMZELX autoinjector by carefully pulling the BIMZELX autoinjector straight up from your skin. The needle guard will automatically cover the needle. **Do not** try to touch the needle.

- Press a clean 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.
- **Repeat steps 1 through 12 with a new BIMZELX autoinjector for a full dose.**
- Make sure you select a new injection site for your second injection. **Do not** use the same site that you used for your first injection.

Step 12: Dispose of (throw away) the used BIMZELX autoinjector (see Figure I).

- Put the used BIMZELX autoinjector in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the BIMZELX autoinjector in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: **<http://www.fda.gov/safesharpsdisposal>**.

- **Do not** recycle your used sharps disposal container.

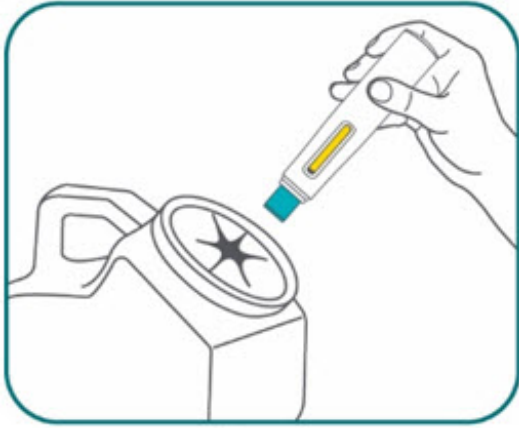


Figure 1

You can sign up to receive sharps containers for BIMZELX autoinjector disposal at no additional cost by going to www.BIMZELX.com or call 1-844-599-2273.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Issued: 10/2023

INSTRUCTIONS for USE
BIMZELX[®] (bim zel' ex)
(bimekizumab-bkzx)
injection, for subcutaneous use
single-dose prefilled syringe

This Instructions for Use contains information on how to inject BIMZELX.

Read this Instructions for Use before using the BIMZELX prefilled syringe and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

For a full dose, 2 injections are required, one after the other. Each BIMZELX prefilled syringe is for one-time (single-dose) use only.

Important Information you Need to Know Before Injecting BIMZELX:

- Your healthcare provider should show you or a caregiver how to prepare and inject BIMZELX using the prefilled syringe for the first time. Do not inject yourself or someone else until you have been shown how to inject BIMZELX the right way. Call your healthcare provider if you have any questions.
- These instructions are for 1 injection only. **For a full dose, 2 injections are required, one after the other.**
- The BIMZELX prefilled syringe has a needle safety feature that will be activated to cover the needle after the injection is finished. The needle safety feature will help to prevent needle stick injuries to anyone who handles the prefilled syringe after injection.

- **Do not** share or reuse your BIMZELX prefilled syringe. You may give or get an infection.
- **Do not** remove the needle cap until just before you give the injection.

How should I store BIMZELX prefilled syringe?

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

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

BIMZELX prefilled syringe parts (see Figure A):

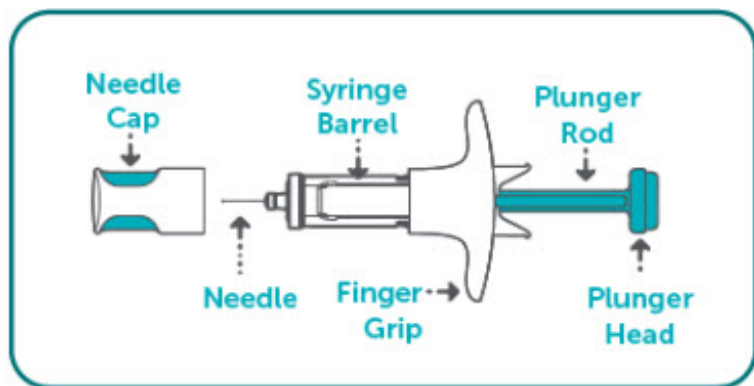


Figure A

Supplies Needed For each BIMZELX injection:

- 1 BIMZELX prefilled syringe

Not provided in the BIMZELX prefilled syringe carton:

- 1 alcohol swab
- 1 clean cotton ball
- 1 sharps disposal container. See, "**Step 12: Dispose of (throw away) the used BIMZELX prefilled syringe**" at the end of this Instructions for Use.

Setting up for your BIMZELX injection.

Step 1: Take the BIMZELX prefilled syringe carton out of the refrigerator. Do not use the BIMZELX prefilled syringe(s) if the carton seal is broken. Throw it away and get a new one.

- **Keep the BIMZELX prefilled syringe in its original carton for 30 to 45 minutes** to warm to room temperature. This will help to reduce discomfort when

injecting.

- **Do not** microwave the prefilled syringe, run hot water over it, or leave it in direct sunlight
- **Do not** shake the prefilled syringe.
- **Do not** take the cap off the prefilled syringe until you are ready to inject.

Step 2: Find a clean, flat, and well-lit work surface, like a table.

Step 3: Gather the supplies for your injection.

Step 4: Wash your hands well with soap and water and dry with a clean towel.

Step 5: Inspect the BIMZELX prefilled syringe (**see Figure B**):

- Remove the BIMZELX prefilled syringe from the carton.
- **Make sure the name BIMZELX appears on the label.**
 - Check the expiration date printed on the label.
 - Check the medicine through the viewing window. The medicine inside should be clear to slightly pearly, and colorless to pale brownish-yellow. You may see air bubble(s) in the liquid. This is normal.
- **Do not use the BIMZELX prefilled syringe, throw it away and get a new one if:**
 - The expiration date printed on the label has passed
 - The medicine is cloudy, discolored, or has particles
 - It looks damaged or has been dropped

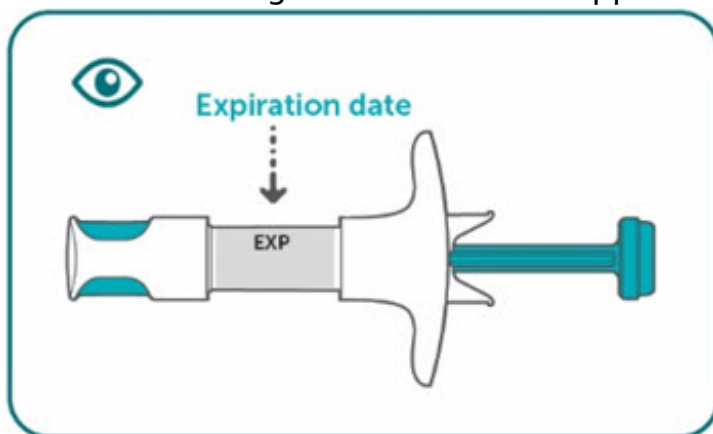
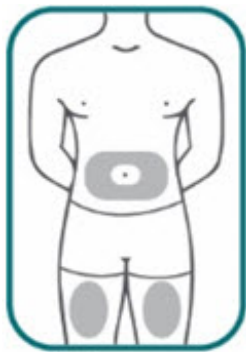


Figure B

Choose and prepare your injection site.

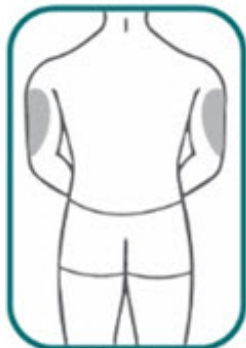
Step 6: Choose and clean your injection site.

- **The sites you may choose for your injection are:**
 - your stomach area (abdomen) or in your thigh (**see Figure C**).
 - the back of your arm (**see Figure D**). BIMZELX may be injected into the back of your arm by a healthcare provider or caregiver only.



Abdomen or thigh

Figure C



Back of arm

Figure D

- **Do not** inject into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis, or within 2 inches of the belly button (navel).
- Choose a different site for each injection. **Do not** use the same injection site 2 times in a row.

Step 7: Prepare your skin.

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

Injecting BIMZELX.

Step 8: Remove the BIMZELX prefilled syringe needle cap.

- Hold the BIMZELX prefilled syringe around the finger grip with one hand. Pull the cap straight off (away from) the BIMZELX prefilled syringe with the other hand (**see Figure E**). You may see a drop of liquid on the tip of the needle, this is normal.
 - **Put** the cap into an FDA-cleared sharps disposal container right away. You will not need it again.
 - **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 BIMZELX prefilled syringe away and call your healthcare provider.
 - **Do not** put the needle cap back on.

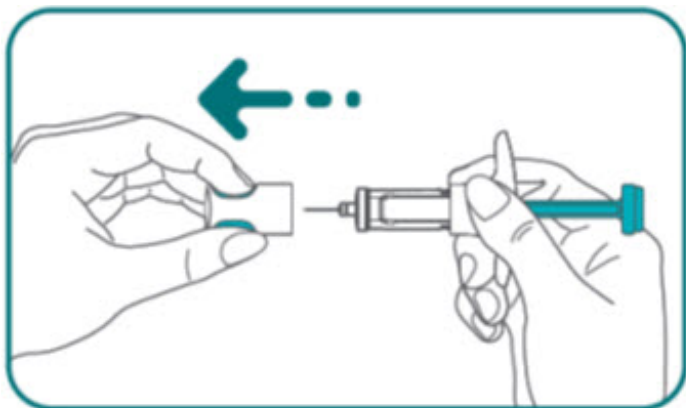


Figure E

Step 9: 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 to make sure that you inject your full dose. Then gently let go of your skin. Make sure the needle is in place (**see Figure F**).

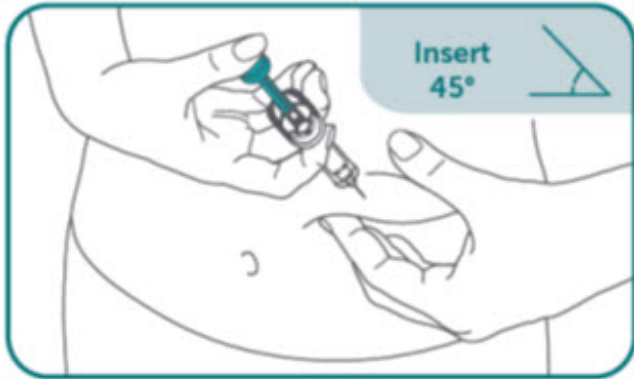


Figure F

Step 10: Firmly push the plunger head all the way down until all the medicine is injected. (**see Figure G**).

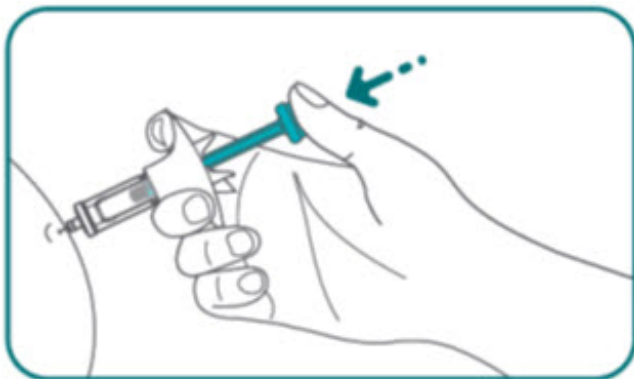


Figure G

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



Figure H

Step 11: Lift your thumb off the plunger head (**see Figure I**). The needle will automatically move back in and lock in place.

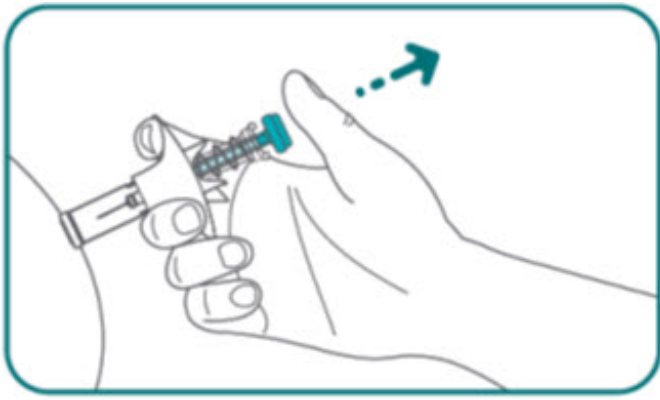


Figure I

- Press a clean cotton ball or gauze pad 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.
- **Repeat steps 1 through 12 with a new BIMZELX prefilled syringe for a full dose.**
- Make sure to select a new injection site for your second injection. **Do not** use the same site that you used for your first injection.

Step 12: Dispose of (throw away) the used BIMZELX prefilled syringe (see Figure J).

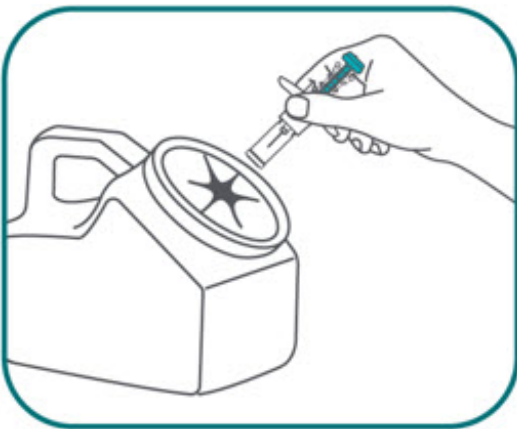


Figure J

- Put the used BIMZELX prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the BIMZELX prefilled syringe in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>.

- **Do not** recycle your used sharps disposal container.

You can sign up to receive sharps containers for BIMZELX syringe disposal at no additional cost by going to www.BIMZELX.com or call 1-844-599-2273.

Manufactured by:

UCB, Inc.

1950 Lake Park Drive Smyrna, GA 30080

US License No. 1736

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: 10/2023

PRINCIPAL DISPLAY PANEL - 160 mg/mL Autoinjector Carton

NDC 50474-781-85

Rx ONLY

ATTENTION: Dispense enclosed
Medication Guide to each patient.

Bimzelx[®]

(bimekizumab-bkzx) Injection

160 mg/mL per autoinjector

FOR SUBCUTANEOUS USE ONLY

Two single-dose autoinjectors.

Each autoinjector delivers 160 mg
in 1 mL of bimekizumab-bkzx.

For a 320 mg dose, two 160 mg
autoinjectors are required.

Bimzelx[®]
(bimekizumab-bkzx) Injection

Each 1 mL autoinjector
contains: 160 mg bimekizumab-bkzx

2 AUTOINJECTORS



NDC 50474-781-85

Rx ONLY

ATTENTION: Dispense enclosed
Medication Guide to each patient.

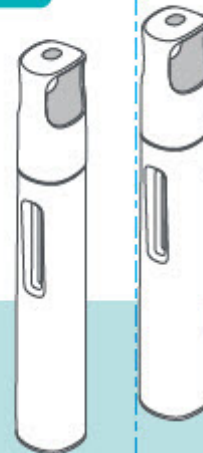
Bimzelx[®]
(bimekizumab-bkzx) Injection

160 mg/mL per autoinjector

FOR SUBCUTANEOUS USE ONLY

**Two single-dose autoinjectors.
Each autoinjector delivers 160 mg
in 1 mL of bimekizumab-bkzx.**

**For a 320 mg dose, two 160 mg
autoinjectors are required.**



Bimzelx[®] is registered trademark
of the UCB Group of Companies.

TUCK FLAP INTO CLOSE



Autoinjector
160 mg bimekizumab-bkzx

2 AUTOINJECTORS

Bimzelx[®]
(bimekizumab-bkzx) Injection
160 mg/mL per autoinjector

Rx ONLY

Each 1 mL autoinjector contains:

Each 1 mL autoinjector contains: 160

2 AUTOINJECTORS



Press here and lift to open



- 160 mg bimekizumab
- 1.23 mg glacial acetic acid
- 16.5 mg glycine
- 0.4 mg polysorbate 80
- 2.83 mg sodium acetate
- Water for Injection, USP

No preservatives. pH 5.1

Recommended Dosage: See prescribing information.

Store refrigerated at 2 to 8°C (36 to 46°F) in the original carton to protect from light.

Do not freeze. Do not shake. Discard unused portion.

When necessary, Bimzelx autoinjector may be stored at room temperature up to 77°F (25°C) in the original carton to protect from light for a single period of up to 30 days. Once Bimzelx autoinjector has been stored at room temperature, do not place back in refrigerator and discard if not used within the 30-day period.

Date removed from refrigerator:

___ / ___ / ___



Manufactured by:
UCB, Inc.
Smyrna, GA 30080
UCB Pharma S.A.
U.S. License No. 1736
Product of Germany

For more information,
visit www.BIMZELX.com

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XXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX

SN:
LOT:
EXP:

NDC: 50474781-85

Start Guide

Bimzelx (bimekizumab) autoinjector
sources, including injection support,
visit www.BIMZELX.com

4. Injection completion



Injection is complete at 2nd "click"

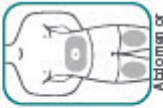


Quick
for using f
For additional res

See enclosed full instructions for
Use booklet.

**For a 320 mg dose, two 160 mg
autoinjectors are required.**

1. Select



- Back of arm
- Thigh
- Wash & dry hands
- Select injection site
- Wipe site with alcohol swab

2. Prepare



- Pull the cap straight off the autoinjector
- DO NOT TOUCH NEEDLE GUARD
- It is normal to see one or more bubbles

3. Inject



- Hold the autoinjector at 90°
- Press the autoinjector against the skin.
- Injection begins at 1st click

**Do not use the BIMZELX autoinjector if the medicine
is cloudy, discolored, or has particles.**
Do not try to inject unless trained by a healthcare provider.

Bimzelx®
(bimekizumab-bkzx) Injection
160 mg/mL per autoinjector



PRINCIPAL DISPLAY PANEL - 160 mg/mL Syringe Carton

NDC 50474-780-79

Rx ONLY

ATTENTION: Dispense enclosed
Medication Guide to each patient.

Bimzelx®
(bimekizumab-bkzx) Injection

160 mg/mL per syringe
FOR SUBCUTANEOUS USE ONLY

Two single-dose prefilled
syringes. Each syringe
delivers 160 mg in 1 mL

of bimekizumab-bkzx.

For a 320 mg dose, two 160 mg
prefilled syringes are required.

Bimzelx[®]
(bimekizumab-bkzx) Injection

NDC 50474-780-79

Rx ONLY

ATTENTION: Dispense enclosed Medication Guide to each patient.

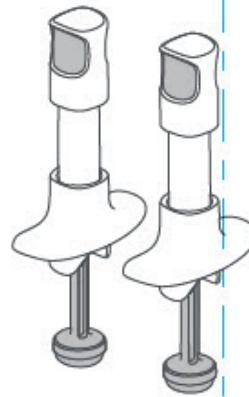
Bimzelx[®]
(bimekizumab-bkzx) Injection

160 mg/mL per syringe

FOR SUBCUTANEOUS USE ONLY

Two single-dose prefilled syringes. Each syringe delivers 160 mg in 1 mL of bimekizumab-bkzx.

For a 320 mg dose, two 160 mg prefilled syringes are required.



↑
LIFT HERE
TO OPEN

TUCK FLAP IN TO CLOSE

Bimzelx[®] is a registered trademark of the UCB Group of Companies.

Each 1 mL prefilled syringe contains:
160 mg bimekizumab-bkzx

2 PREFILLED SYRINGES



Each 1 mL prefilled syringe contains:
160 mg bimekizumab-bkzx

2 PREFILLED SYRINGES

Bimzelx[®]
(bimekizumab-bkzx) Injection
160 mg/mL per syringe

Rx ONLY

Each 1 mL prefilled syringe contains:

- 160 mg bimekizumab
- 1.23 mg glacial acetic acid
- 16.5 mg glycine
- 0.4 mg polysorbate 80
- 2.83 mg sodium acetate
- Water for Injection, USP

No preservatives. pH 5.1

Recommended Dosage: See prescribing information.

Store refrigerated at 2 to 8°C (36 to 46°F) in the original carton to protect from light.

Do not freeze. Do not shake. Discard unused portion.

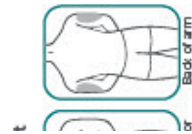
When necessary, Bimzelx syringe may be stored at room temperature up to 77°F (25°C) in the original carton to protect from light for a single period of up to 30 days. Once Bimzelx syringe has been stored at room temperature, do not place back in refrigerator and discard if not used within

Read the enclosed full instructions booklet.

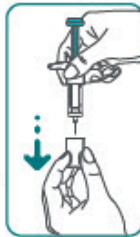
Two 320 mg dose, 50 mg syringes required.

Quick Start Guide

for using BIMZELX (bimekizumab) prefilled syringe.
For additional resources, including injection support, visit www.BIMZELX.com



2. Prepare



- Pull the cap straight off the syringe
- **DO NOT TOUCH NEEDLE**
- Do not let needle touch any surface
- If it is normal to see one or more bubbles

3. Pinch and inject



- Pinch cleaned skin
- Insert needle at 45° angle with a quick dart-like motion
- Release pinched skin, then slowly push plunger until syringe is empty
- Immediately repeat steps for 2nd injection to complete dose. When using second syringe, inject in different site

4. Syringes disposal



- Dispose of used syringes in FDA-cleaned disposal container after they have been used

Wash hands with alcohol swab



Do not use the BIMZELX prefilled syringes if the medicine is cloudy, discolored, or has particles.
Do not try to inject unless trained by a healthcare provider.



Press here and lift to open

c1B73924A



Manufactured by:
UCB, Inc.
Smyrna, GA 30080
UCB Pharma S.A.
U.S. License No. 1736
Product of Germany

Date removed from refrigerator:

___ / ___ / ___

For more information, visit www.BIMZELX.com



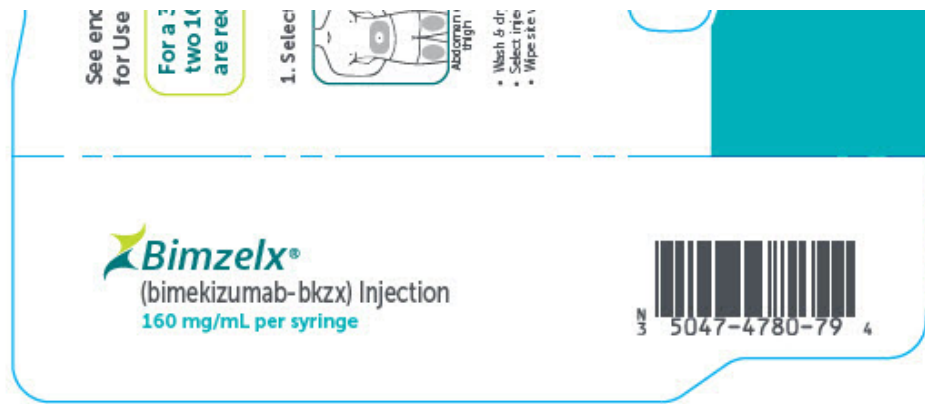
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NDC: 5047478079

SN: XXXXXXXXXXXXXXXX

LOT: XXXXXXXXXXXXXXXX

EXP: XXXXXXXXXXXXXXXX



BIMZELX

bimekizumab injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50474-781
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bimekizumab (UNII: 09495UIM6V) (bimekizumab - UNII:09495UIM6V)	bimekizumab	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
acetic acid (UNII: Q40Q9N063P)	1.23 mg in 1 mL
glycine (UNII: TE7660XO1C)	16.5 mg in 1 mL
polysorbate 80 (UNII: 6OZP39ZG8H)	0.4 mg in 1 mL
SODIUM ACETATE (UNII: 4550K0SC9B)	2.83 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (brownish to yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50474-781-85	2 in 1 CARTON	10/17/2023	
1		1 mL in 1 SYRINGE, GLASS; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

2	NDC:50474-781-87	2 in 1 CARTON	10/17/2023	
2		1 mL in 1 SYRINGE, GLASS; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761151	10/17/2023	

BIMZELX

bimekizumab injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50474-780
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bimekizumab (UNII: 09495UIM6V) (bimekizumab - UNII:09495UIM6V)	bimekizumab	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
acetic acid (UNII: Q40Q9N063P)	1.23 mg in 1 mL
glycine (UNII: TE7660XO1C)	16.5 mg in 1 mL
polysorbate 80 (UNII: 6OZP39ZG8H)	0.4 mg in 1 mL
SODIUM ACETATE (UNII: 4550K0SC9B)	2.83 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50474-780-79	2 in 1 CARTON	10/17/2023	
1		1 mL in 1 SYRINGE, GLASS; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761151	10/17/2023	

