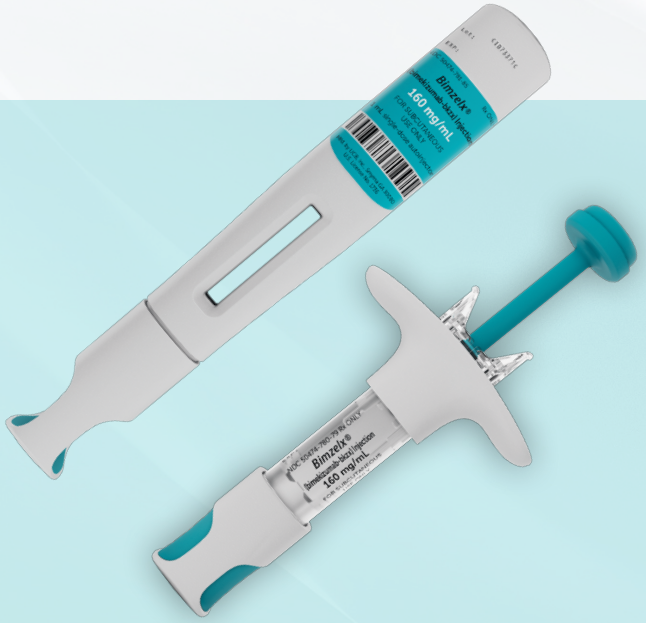
Bimzelx®
(bimekizumab-bkzx)



Dosing Guide

For All BIMZELX Indications

For more information on BIMZELX, visit BIMZELXhcp.com.

IMPORTANT SAFETY INFORMATION

BIMZELX may increase the risk of suicidal ideation and behavior. Advise patients and caregivers to monitor and seek medical attention for the emergence or worsening of depression, suicidal ideation, or other mood changes. BIMZELX may increase the risk of infection. Instruct patients to report signs and symptoms of clinically important infection during treatment. Should such an infection occur, discontinue BIMZELX until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with BIMZELX. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and periodically during treatment with BIMZELX. Avoid use in patients with acute liver disease or cirrhosis, and in patients with active IBD. Avoid use of live vaccines in BIMZELX patients.

Please see additional Important Safety Information on page 9.
Please refer to the full Prescribing Information provided by the UCB representative and visit BIMZELXhcp.com.

BIMZELX® (bimekizumab-bkzx) Indications

Approved for a breadth of indications

PSO

For the treatment of adult patients with moderate-to-severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy

PsA

For the treatment of adult patients with active psoriatic arthritis (PsA)

nr-axSpA

For the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

AS

For the treatment of adult patients with active ankylosing spondylitis (AS)

HS

For the treatment of adult patients with moderate-to-severe hidradenitis suppurativa (HS)

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Bimzelx® (bimekizumab-bkzx)

Device and Packaging Options

	Formulation	Carton dimensions	Strength	Package size	NDC*
Dermatology	 Single-dose autoinjectors	 7.68in (l) x 5.16in (w) x 1.65in (d)	160 mg/mL per autoinjector	Carton of two (2) 160 mg/mL single-dose autoinjectors	50474-0781-85
Dermatology	 Single-dose prefilled syringes	 6.69in (l) x 5.83in (w) x 1.65in (d)	160 mg/mL per syringe	Carton of two (2) 160 mg/mL single-dose prefilled syringes	50474-0780-79
Dermatology	 Single-dose autoinjector	 7.68in (l) x 5.16in (w) x 1.65in (d)	320 mg/2 mL (160 mg/mL) per autoinjector	Carton of one (1) 320 mg/2 mL (160 mg/mL) single-dose autoinjector	50474-0782-84
Dermatology	 Single-dose prefilled syringe	 6.69in (l) x 5.83in (w) x 1.65in (d)	320 mg/2 mL (160 mg/mL) per syringe	Carton of one (1) 320 mg/2 mL (160 mg/mL) single-dose prefilled syringe	50474-0783-78
Rheumatology	 Single-dose autoinjector	 7.68in (l) x 5.16in (w) x 1.65in (d)	160 mg/mL per autoinjector	Carton of one (1) 160 mg/mL single-dose autoinjector	50474-0781-84
Rheumatology	 Single-dose prefilled syringe	 6.69in (l) x 5.83in (w) x 1.65in (d)	160 mg/mL per syringe	Carton of one (1) 160 mg/mL single-dose prefilled syringe	50474-0780-78

*For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

Storage Information

- **Cartons should be refrigerated between 2°C and 8°C (36°F and 46°F).** 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.
- Keep in original carton to protect from light. Do not freeze. Do not use beyond expiration date

Shelf Life

- The shelf life of BIMZELX is 36 months

mg, milligram; mL, milliliter; NDC, National Drug Code.

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Bimzelx® (bimekizumab-bkzx)

Device Options

160 mg/mL

Prefilled Syringe

1 mL
160 mg

Autoinjector

320 mg/2 mL (160 mg/mL)

Prefilled Syringe

2 mL
320 mg
(160 mg/mL)

Autoinjector

mg, milligram; mL, milliliter.

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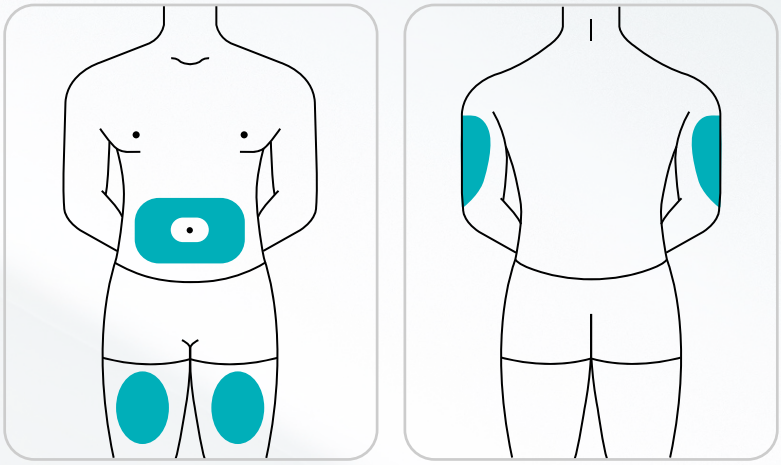
Bimzelx® (bimekizumab-bkzx)

Administration



Patient Injection Sites

BIMZELX® can be self-administered in the thighs or abdomen, or with assistance, in the back of the upper arm

- Patients/and or caregivers should be trained prior to administering BIMZELX®
- Patients may need 2 BIMZELX autoinjectors to achieve the prescribed dose
- Each dose of BIMZELX should be injected at a different anatomic location (such as thighs, abdomen, or back of upper arm*)
- Injection into the upper, outer arm may only be performed by an HCP or caregiver
- Avoid areas where skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis
- If a dose of BIMZELX is missed, instruct the patient to inject the dose as soon as possible and to take the next dose at the regularly scheduled time

Instruct patients and/or caregivers to review injection training resources at https://www.bimzelx.com/about-bimzelx/dosing For full injection instructions, refer patients to the Instructions for Use.

It's important to **instruct patients switching from the 1 mL autoinjector to the 2 mL autoinjector** that there are differences in the administration instructions and to **carefully read the Instructions for Use for the 2 mL autoinjector.**

HCP, healthcare provider; mg, milligram; mL, milliliter.

*Different anatomical locations should be used for each injection. The same injection site should not be used two times in a row.

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Bimzelx® (bimekizumab-bkzx)

Dosing and Administration for Patients With PSO

PSO

The recommended dosage of BIMZELX® is 320 mg (can be given as either 2 subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter.

INITIATION DOSE

WEEK 0	WEEK 4	WEEK 8	WEEK 12	WEEK 16
320 mg	320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL
OR	OR	OR	OR	OR
1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL

MAINTENANCE DOSE

Q8W

320 mg
2 x 160 mg/mL
OR
1 x 320 mg/2 mL

For patients weighing 120 kg (264.5 lb) or more, consider a dose of 320 mg every 4 weeks after week 16

kg, kilogram; lb, pound; mg, milligram; mL, milliliter; PSO, psoriasis; Q8W, every 8 weeks.

Please see additional Important Safety Information on page 9.
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Bimzelx® (bimekizumab-bkzx)

Dosing and Administration for HS

HS

The recommended dosage of BIMZELX® is 320 mg (can be given as either 2 subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter.

INITIATION DOSE

WEEK 0	WEEK 2	WEEK 4	WEEK 6	WEEK 8
320 mg	320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL
OR	OR	OR	OR	OR
1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL

WEEK 10	WEEK 12	WEEK 14	WEEK 16
320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL	2 x 160 mg/mL
OR	OR	OR	OR
1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL	1 x 320 mg/2 mL

MAINTENANCE DOSE

Q4W

320 mg
2 x 160 mg/mL
OR
1 x 320 mg/2 mL

HS, hidradenitis suppurativa; mg, milligram; mL, milliliter; Q4W, every 4 weeks.

Please see additional Important Safety Information on page 9.
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Bimzelx® (bimekizumab-bkzx)

Dosing and Administration for PsA, AS, and nr-axSpA

PsA nr-axSpA AS

The recommended dosage of BIMZELX® is 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks

For patients with PsA and coexisting PSO, use the PSO dose

AS, ankylosing spondylitis; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis; PSO, psoriasis; Q4W, every 4 weeks.

Please see additional Important Safety Information on page 9.
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Bimzelx® (bimekizumab-bkzx)

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior

BIMZELX® (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been definitively established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections, including serious infections. 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 suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

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 for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities

Elevated serum transaminases were reported in clinical trials with BIMZELX. 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 use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease

Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. 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.

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.

MOST COMMON ADVERSE REACTIONS

Most common (≥ 1%) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

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