PSO PsA nr-axSpA AS HS

Bimzelx® (bimekizumab-bkzx)

PRODUCT AVAILABILITY ANNOUNCEMENT
NDCs IN CHANNEL

BIMZELX is indicated for the

- Treatment of adult patients **moderate-to-severe plaque psoriasis (PSO)** who are candidates for systemic therapy or phototherapy
- Treatment of adult patients with **active psoriatic arthritis (PsA)**
- Treatment of adult patients with **active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation
- Treatment of adult patients with **active ankylosing spondylitis (AS)**
- Treatment of adult patients with **moderate-to-severe hidradenitis suppurativa (HS)**

NDCs Available: Stocking and Ordering Information

	Formulation		NDC	Strength	Package size
Dermatology		Single-dose autoinjectors	50474-0781-85	160 mg/mL per autoinjector	Carton of two (2) 160 mg/mL single-dose autoinjectors
Dermatology		Single-dose prefilled syringes	50474-0780-79	160 mg/mL per syringe	Carton of two (2) 160 mg/mL single-dose prefilled syringes
Dermatology		Single-dose autoinjector	50474-0782-84	320 mg/2 mL (160mg/mL) per autoinjector	Carton of one (1) 320 mg/2 mL (160mg/mL) single-dose autoinjector
Dermatology		Single-dose prefilled syringe	50474-0783-78	320 mg/2 mL (160mg/mL) per syringe	Carton of one (1) 320 mg/2 mL (160mg/mL) single-dose prefilled syringe
Rheumatology		Single-dose autoinjector	50474-0781-84	160 mg/mL per autoinjector	Carton of one (1) 160 mg/mL single-dose autoinjector
Rheumatology		Single-dose prefilled syringe	50474-0780-78	160 mg/mL per syringe	Carton of one (1) 160 mg/mL single-dose prefilled syringe

Click or scan to download the BIMZELX Wholesale Order Entry Form

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.

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.

Please refer to the full Prescribing Information provided by the UCB representative, and visit BIMZELXhcp.com.
For more information on BIMZELX, call UCBCares® at 1-844-599-CARE (2273).

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