PRESCRIBING INFORMATION FOR HCPs IN REPUBLIC OF IRELAND

(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

Bimzelx® (bimekizumab)

Active Ingredient: bimekizumab – *solution for injection in pre-filled syringe or pre-filled pen: 160 mg of bimekizumab in 1 mL of solution (160 mg/mL), 320 mg of bimekizumab in 2 mL of solution (160 mg/mL)*.

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

Dosage and Administration: Should be initiated and supervised by a physician experienced in the diagnosis and treatment of conditions for which it is indicated. **Recommended dose:** *Plaque Psoriasis:* 320 mg (given as two subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. *Psoriatic arthritis:* 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis. After 16 weeks, regular assessment of efficacy is recommended and if a sufficient clinical response in joints cannot be maintained, a switch to 160 mg every 4 weeks can be considered. *Axial spondyloarthritis (nr-axSpA and AS):* 160 mg (given as 1 subcutaneous injection) every 4 weeks. For patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response. Consider discontinuing if no improvement by 16 weeks of treatment. *Hidradenitis suppurativa*: 320 mg (given as 2 subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) every 2 weeks up to Week 16 and every 4 weeks thereafter. *Renal or hepatic impairment:* No dose adjustment needed. *Elderly:* No dose adjustment needed.

Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject.

Contraindications: Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis).

Warnings and Precautions*:* Record name and batch number of administered product. *Infection:* Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity*: Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations*: Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations.

Interactions: A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered.

Fertility, pregnancy and lactation: Women of child-bearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility. **Driving and use of machines**: No or negligible influence on ability to drive and use machines. **Adverse Effects: Refer to SmPC for full information.** *Very Common (≥ 1/10):* upper respiratory tract infection*; Common (≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue, Vulvovaginal mycotic infection (including vulvovaginal candidiasis) *; Uncommon (≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. **Storage precautions:** Store in a refrigerator (2ºC – 8ºC), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25ºC for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

Legal Category: POM

Marketing Authorisation Numbers: EU/1/21/1575/002 (Pack size of 2 x 1ml Pre-filled Syringes), EU/1/21/1575/006 (Pack size of 2 x 1ml Pre-filled Pens), EU/1/21/1575/009 (Pack size of 1 x 2ml Pre-filled Syringe), EU/1/21/1575/0011 (Pack size of 1 x 2ml Pre-filled Pen).

Marketing Authorisation Holder: UCB Pharma S.A., Allée de la Recherche 60, B-1070 Brussels, Belgium.

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Bimzelx is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie/homepage/about-us/report-an-issue. Adverse events should also be reported to UCB (Pharma) Ireland Ltd at ucbcares.ie@ucb.com or 1800 930075