

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled syringe
Bimzelx 160 mg solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bimzelx 160 mg solution for injection in pre-filled syringe

Each pre-filled syringe contains 160 mg of bimekizumab in 1 mL.

Bimzelx 160 mg solution for injection in pre-filled pen

Each pre-filled pen contains 160 mg of bimekizumab in 1 mL.

Bimekizumab is a humanised IgG1 monoclonal antibody produced in a genetically engineered Chinese hamster ovary (CHO) cell line by recombinant DNA technology.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection)

The solution is clear to slightly opalescent and pale brownish-yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

4.2 Posology and method of administration

Bimzelx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis.

Posology

The recommended dose for adult patients with plaque psoriasis is 320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter.

Consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment.

Special populations

Overweight patients

For some patients with 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 (see section 5.1).

Elderly (≥ 65 years)

No dose adjustment is required (see section 5.2).

Renal or hepatic impairment

Bimekizumab has not been studied in these patient populations. Dose adjustments are not considered necessary based on pharmacokinetics (see section 5.2).

Paediatric population

The safety and efficacy of bimekizumab in children and adolescents below the age of 18 years have not been established. No data are available.

Method of administration

This medicinal product is administered by subcutaneous injection.

Suitable areas for injection include thigh, abdomen and upper arm. Injection sites should be rotated and injections should not be given into psoriasis plaques or areas where the skin is tender, bruised, erythematous, or indurated.

The pre-filled syringe or pre-filled pen must not be shaken.

After proper training in subcutaneous injection technique, patients may self-inject Bimzelx with the pre-filled syringe or pre-filled pen if their physician determines that it is appropriate and with medical follow-up as necessary. Patients should be instructed to inject the full amount of Bimzelx according to the instructions for use provided in the package leaflet.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Clinically important active infections (e.g. active tuberculosis, see section 4.4).

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Infections

Bimekizumab may increase the risk of infections such as upper respiratory tract infections and oral candidiasis (see section 4.8).

Caution should be exercised when considering the use of bimekizumab in patients with a chronic infection or a history of recurrent infection. Treatment with bimekizumab must not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated (see section 4.3).

Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a clinically important infection or is not responding to standard therapy, the patient should be monitored carefully and bimekizumab should not be administered until the infection resolves.

Pre-treatment evaluation for tuberculosis (TB)

Prior to initiating treatment with bimekizumab, patients should be evaluated for TB infection. Bimekizumab should not be given in patients with active TB (see section 4.3). Patients receiving bimekizumab should be monitored for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating bimekizumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Inflammatory bowel disease

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab (see section 4.8). Bimekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.

Hypersensitivity

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, administration of bimekizumab should be discontinued immediately and appropriate therapy initiated.

Vaccinations

Prior to initiating therapy with bimekizumab, completion of all age appropriate immunizations according to current immunization guidelines should be considered.

Live vaccines should not be given in patients treated with bimekizumab.

Patients treated with bimekizumab may receive inactivated or non-live vaccinations. Healthy individuals who received a single 320 mg dose of bimekizumab two weeks prior to vaccination with an inactivated seasonal influenza vaccine had similar antibody responses compared to individuals who did not receive bimekizumab prior to vaccination.

Excipients

This medicinal product contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially “sodium free”.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

There is no direct evidence for the role of IL-17A or IL-17F in the expression of CYP450 enzymes. The formation of some CYP450 enzymes is suppressed by increased levels of cytokines during chronic inflammation. Thus, anti-inflammatory treatments, such as with the IL-17A and IL-17F inhibitor bimekizumab, may result in normalisation of CYP450 levels with accompanying lower exposure of CYP450-metabolised medicinal products. Therefore, 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. On initiation of bimekizumab therapy in patients being treated with these types of medicinal products, therapeutic monitoring should be considered.

Live vaccines should not be given concurrently with bimekizumab (see section 4.4).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment.

Pregnancy

There is a limited amount of data on the use of bimekizumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Bimzelx during pregnancy.

Breast-feeding

It is unknown whether bimekizumab is excreted in human milk. 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 taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

The effect of bimekizumab on human fertility has not been evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Bimzelx has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions were upper respiratory tract infections (14.5%) (most frequently nasopharyngitis) and oral candidiasis (7.3%).

Tabulated list of adverse reactions

Adverse reactions from clinical studies (Table 1) are classified by MedDRA System Organ Class and frequency, using the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Table 1: List of adverse reactions

System Organ Class	Frequency	Adverse reaction
Infections and infestations	Very common	Upper respiratory tract infections
	Common	Oral candidiasis, Tinea infections, Ear infections, Herpes simplex infections, Oropharyngeal candidiasis, Gastroenteritis, Folliculitis
	Uncommon	Mucosal and cutaneous candidiasis (including oesophageal candidiasis), Conjunctivitis
Blood and lymphatic system disorders	Uncommon	Neutropenia
Nervous System disorders	Common	Headache
Gastrointestinal disorders	Uncommon	Inflammatory bowel disease
Skin and subcutaneous tissue disorders	Common	Dermatitis and eczema, Acne
General disorders and administration site conditions	Common	Injection site reactions ^a , Fatigue
^{a)} Includes: injection site erythema, reaction, oedema, pain, swelling.		

Description of selected adverse reactions

Infections

In the placebo-controlled period of Phase III clinical studies in plaque psoriasis, infections were reported in 36.0% of patients treated with bimekizumab for up to 16 weeks compared with 22.5% of patients treated with placebo. Serious infections occurred in 0.3% of patients treated with bimekizumab and 0% treated with placebo.

The majority of infections consisted of non-serious mild to moderate upper respiratory tract infections such as nasopharyngitis. There were higher rates of oral and oropharyngeal candidiasis in patients treated with bimekizumab consistent with the mechanism of action (7.3% and 1.2% respectively compared to 0% for placebo-treated patients). More than 98% of cases were non-serious, mild or moderate in severity, and did not require treatment discontinuation. A slightly higher incidence of oral candidiasis was reported in patients < 70 kg (8.5% *versus* 7.0% in patients ≥ 70 kg).

Over the entire treatment period of Phase III studies in plaque psoriasis, infections were reported in 63.2% of patients treated with bimekizumab (120.4 per 100 patient-years). Serious infections were reported in 1.5% of patients treated with bimekizumab (1.6 per 100 patient-years) (see section 4.4).

Neutropenia

Neutropenia was observed with bimekizumab in phase III clinical studies in plaque psoriasis. Over the entire treatment period of Phase III studies, neutropenia grade 3/4 were observed in 1% of patients treated with bimekizumab. Most cases were transient and did not require treatment discontinuation. No serious infections were associated with neutropenia.

Hypersensitivity

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors.

Immunogenicity

Approximately 45% of plaque psoriasis patients treated with bimekizumab up to 56 weeks at the recommended dosing regimen (320 mg every 4 weeks up to week 16 and 320 mg every 8 weeks thereafter) developed anti-drug antibodies. Of the patients who developed anti-drug antibodies, approximately 34% (16% of all patients treated with bimekizumab) had antibodies that were classified as neutralising. No evidence of altered clinical response, or significantly altered safety profile was associated with anti-bimekizumab antibodies development.

Elderly patients (≥65 years)

Elderly patients may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab. In the placebo-controlled period of Phase III clinical studies in plaque psoriasis, oral candidiasis was observed in 18.2% of patients ≥65 years *versus* 6.3 % in <65 years, dermatitis and eczema in 7.3% of patients ≥65 years *versus* 2.8% in <65 years.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).

4.9 Overdose

Single doses of 640 mg intravenously or 640 mg subcutaneously, followed by 320 mg subcutaneously every two weeks for five doses have been administered in clinical studies without dose-limiting toxicity. In the event of overdose, it is recommended that the patient be monitored for any signs and symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, interleukin inhibitors, ATC code: L04AC21

Mechanism of action

Bimekizumab is a humanised IgG1/κ monoclonal antibody that selectively binds with high affinity to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex. Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated inflammatory diseases including plaque psoriasis. Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis. From

in vitro models, bimekizumab was shown to inhibit psoriasis-related gene expression and cytokine production to a greater extent than inhibition of IL-17A alone.

Clinical efficacy and safety

The safety and efficacy of bimekizumab was evaluated in 1,480 patients with moderate to severe plaque psoriasis in three Phase 3 multicenter, randomised, placebo and/or active comparator-controlled studies. Patients were at least 18 years of age, had a Psoriasis Area and Severity Index (PASI) score ≥ 12 and Body Surface Area (BSA) affected by psoriasis (PSO) $\geq 10\%$, an Investigators Global Assessment (IGA) score ≥ 3 on a 5-point scale and were candidates for systemic psoriasis therapy and/or phototherapy. The efficacy and safety of bimekizumab were evaluated *versus* placebo and ustekinumab (BE VIVID – PS0009), *versus* placebo (BE READY – PS0013) and *versus* adalimumab (BE SURE - PS0008).

The BE VIVID study evaluated 567 patients for 52 weeks where patients were randomised to receive either bimekizumab 320 mg every 4 weeks, ustekinumab (45 mg or 90 mg, depending on patient weight, at baseline and week 4 and then every 12 weeks), or placebo for an initial 16 weeks, followed by bimekizumab 320 mg every 4 weeks.

The BE READY study evaluated 435 patients for 56 weeks. Patients were randomised to receive bimekizumab 320 mg every 4 weeks or placebo. At week 16, patients who achieved a PASI 90 response entered the 40-week randomised withdrawal period. Patients initially randomised to bimekizumab 320 mg every 4 weeks were re-randomised to either bimekizumab 320 mg every 4 weeks or bimekizumab 320 mg every 8 weeks or placebo (i.e. withdrawal of bimekizumab). Patients initially randomised to placebo continued to receive placebo provided they were PASI 90 responders. Patients who did not achieve a PASI 90 response at week 16 entered an open-label escape arm and received bimekizumab 320 mg every 4 weeks for 12 weeks. Patients who relapsed (did not achieve PASI 75 response) during the randomised withdrawal period also entered the 12-week escape arm.

The BE SURE study evaluated 478 patients for 56 weeks. Patients were randomised to receive either bimekizumab 320 mg every 4 weeks through week 56, bimekizumab 320 mg every 4 weeks through week 16 followed by bimekizumab 320 mg every 8 weeks through week 56 or adalimumab as per labeling recommendation through Week 24 followed by bimekizumab 320 mg every 4 weeks through week 56.

Baseline characteristics were consistent across all 3 studies: patients were predominantly male (70.7%) and white (84.1%), with a mean age of 45.2 years (18 to 83 years), and 8.9% were ≥ 65 years of age. The median baseline BSA was 20%, the median baseline PASI score was 18 and the baseline IGA score was severe in 33% of patients. The median baseline scores for Patient Symptoms Diary (PSD) pain, itch and scaling items ranged between 6 and 7 on a 0-10 points scale and the median baseline Dermatology Life Quality Index (DLQI) total score was 9.

Across all 3 studies, 38% of patients had received a prior biologic therapy; 23% had received at least one anti-IL17 agent (primary anti-IL17 failures were excluded) and 13% had received at least one TNF-antagonist. Twenty-two percent were naïve to any systemic therapy (including non-biologic and biologic) and 39% of patients had received prior phototherapy or photochemotherapy.

The efficacy of bimekizumab was evaluated with respect to impact on skin disease overall, specific body locations (scalp, nails, palms and soles), patient reported symptoms and impact on quality of life. The two co-primary endpoints in all 3 studies were the proportion of patients who achieved 1) a PASI 90 response and 2) an IGA “clear or almost clear” (IGA 0/1 with at least two points improvement from baseline) response at week 16. PASI 100, IGA 0 response at week 16 and PASI 75 response at week 4 were secondary endpoints in all 3 studies.

Skin disease overall

Treatment with bimekizumab resulted in significant improvement across efficacy endpoints compared to placebo, ustekinumab or adalimumab at week 16. The main efficacy results are shown in Table 2.

Table 2: Summary of clinical responses in BE VIVID, BE READY and BE SURE

	BE VIVID			BE READY		BE SURE	
	Placebo (N= 83)	Bimekizumab 320 mg Q4W (N= 321)	Ustekinumab (N=163)	Placebo (N= 86)	Bimekizumab 320 mg Q4W (N= 349)	Bimekizumab 320 mg Q4W (N= 319)	Adalimumab (N= 159)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
PASI 100 Week 16	0 (0.0)	188 (58.6) ^a	34 (20.9)	1 (1.2)	238 (68.2) ^a	194 (60.8) ^a	38 (23.9)
PASI 90 Week 16	4 (4.8)	273 (85.0) ^{a, b}	81 (49.7)	1 (1.2)	317 (90.8) ^a	275 (86.2) ^a	75 (47.2)
PASI 75 Week 4	2 (2.4)	247 (76.9) ^{a, b}	25 (15.3)	1 (1.2)	265 (75.9) ^a	244 (76.5) ^a	50 (31.4)
Week 16	6 (7.2)	296 (92.2)	119 (73.0)	2 (2.3)	333 (95.4)	295 (92.5)	110 (69.2)
IGA 0 Week 16	0 (0.0)	188 (58.6) ^a	36 (22.1)	1 (1.2)	243 (69.6) ^a	197 (61.8)	39 (24.5)
IGA 0/1 Week 16	4 (4.8)	270 (84.1) ^{a, b}	87 (53.4)	1 (1.2)	323 (92.6) ^a	272 (85.3) ^a	91 (57.2)
Absolute PASI ≤ 2 Week 16	3 (3.6)	273 (85.0)	84 (51.5)	1 (1.2)	315 (90.3)	280 (87.8)	86 (54.1)
PSD Pain improvement ≥4 (N) Week 16	(N=48) 5 (10.4)	(N=190) 140 (73.7)	(N=90) 54 (60.0)	(N=49) 0 (0.0)	(N=209) 148 (70.8)	(N=222) 143 (64.4)	(N=92) 43 (46.7)
PSD Itch improvement ≥4 (N) Week 16	(N=53) 6 (11.3)	(N=222) 151 (68.0)	(N=104) 57 (54.8)	(N=60) 0 (0.0)	(N=244) 161 (66.0)	(N=248) 153 (61.7)	(N=107) 42 (39.3)
PSD Scaling improvement ≥4 (N) Week 16	(N=56) 6 (10.7)	(N=225) 171 (76.0)	(N=104) 59 (56.7)	(N=65) 1 (1.5)	(N=262) 198 (75.6)	(N=251) 170 (67.7)	(N= 109) 42 (38.5)

Bimekizumab 320 mg Q4W= bimekizumab every 4 weeks. Non-Responder Imputation (NRI) is used.

IGA 0/1 response was defined as Clear (0) or Almost Clear (1) with at least a 2-category improvement from Baseline at week 16. IGA 0 response was defined as Clear (0) with at least a 2-category improvement from Baseline at week 16.

PSD is a Patient Symptoms Diary, also referred to as Psoriasis Symptoms and Impacts Measure (P-SIM), measuring psoriasis symptom severity on a scale from 0 (no symptoms) to 10 (very severe symptoms). Response is defined as a decrease ≥4 from baseline to week 16 for pain, itch and scaling on a scale from 0 to 10.

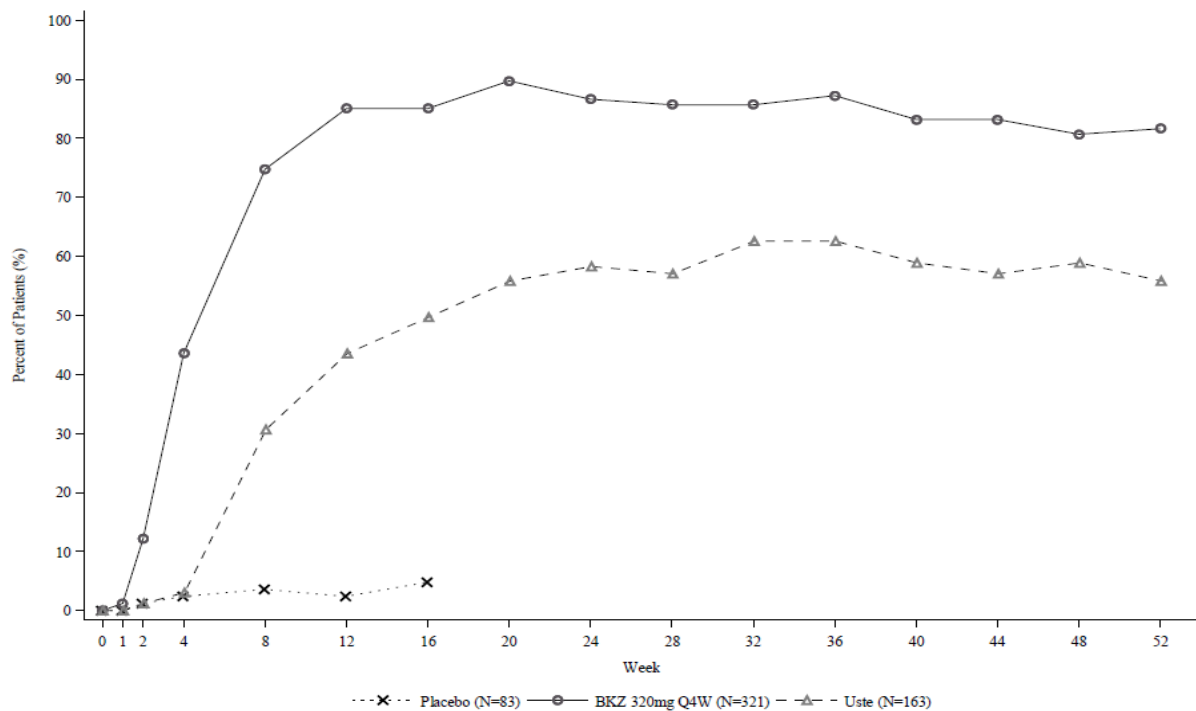
a) p<0.001 *versus* placebo (BE VIVID and BE READY), *versus* adalimumab (BE SURE), adjusted for multiplicity.

b) p<0.001 *versus* ustekinumab (BE VIVID), adjusted for multiplicity.

Bimekizumab was associated with a rapid onset of efficacy. In BE VIVID, at week 2 and week 4, PASI 90 response rates were significantly higher for bimekizumab-treated patients (12.1% and 43.6% respectively) compared to placebo (1.2% and 2.4% respectively) and ustekinumab (1.2% and 3.1% respectively).

In the BE VIVID study, at week 52, bimekizumab-treated patients (every 4 weeks) achieved significantly higher response rates than the ustekinumab-treated patients on the endpoints of PASI 90 (81.9% bimekizumab vs 55.8% ustekinumab, p<0.001), IGA 0/1 (78.2% bimekizumab vs 60.7% ustekinumab, p<0.001) and PASI 100 (64.5% bimekizumab vs 38.0% ustekinumab).

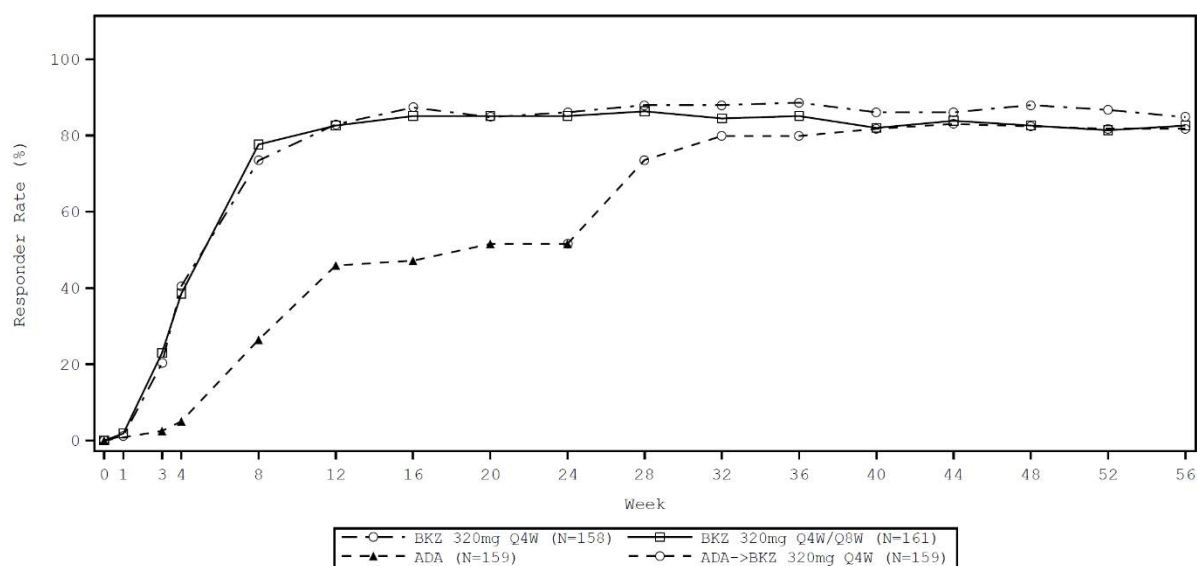
Figure 1: PASI 90 responder rates over time in BE VIVID



BKZ 320 mg Q4W=bimekizumab every 4 weeks; Uste=ustekinumab. NRI is used.

In the BE SURE study at week 24, a significantly higher percentage of patients treated with bimekizumab (Q4W/Q4W and Q4W/Q8W combined dosing arms) achieved PASI 90 and IGA 0/1 responses as compared with adalimumab (85.6% and 86.5% respectively vs 51.6% and 57.9% respectively, $p < 0.001$). At week 56, 70.2% of patients treated with bimekizumab Q8W achieved a PASI 100 response. Among the 65 adalimumab non-responders at week 24 ($< \text{PASI } 90$), 78.5% achieved a PASI 90 response after 16 weeks of treatment with bimekizumab. The safety profile observed in patients who switched from adalimumab to bimekizumab without a wash-out period was similar to patients who initiated bimekizumab after wash out of prior systemic therapies.

Figure 2: PASI 90 responder rates over time in BE SURE



BKZ 320 mg Q4W = bimekizumab every 4 weeks; BKZ 320 mg Q8W = bimekizumab every 8 weeks; ADA= adalimumab. Patients in the BKZ Q4W/Q8W group switched from Q4W to Q8W dosing at week 16. Patients in the ADA/BKZ 320 mg Q4W group switched from ADA to BKZ Q4W at week 24. NRI is used.

The efficacy of bimekizumab was demonstrated regardless of age, gender, race, disease duration, body weight, PASI baseline severity and previous treatment with a biologic. Bimekizumab was efficacious in prior biologic exposed patients, including anti-TNF / anti IL-17 and in systemic treatment-naïve patients. Efficacy in patients with primary failure to anti-IL17 has not been investigated.

Based on population PK/ PD analysis and supported by clinical data, patients with higher body weight (≥ 120 kg) who did not achieve complete skin clearance at week 16 benefited from continued bimekizumab 320 mg every four weeks (Q4W) after the initial 16 weeks of treatment. In the BE SURE study, patients received bimekizumab 320 mg Q4W through week 16, followed by either Q4W or every eight weeks (Q8W) dosing through week 56, regardless of responder status at week 16. Patients in the ≥ 120 kg group (N=37) on the Q4W maintenance regimen showed greater improvement in PASI100 between week 16 (23.5%) and week 56 (70.6%) compared to those on the Q8W maintenance regimen (week 16: 45.0% vs week 56: 60.0%).

Improvements were observed in psoriasis involving the scalp, nails, palms and soles in patients treated with bimekizumab at week 16 (see Table 3).

Table 3: Scalp, palmoplantar and nail responses in BE VIVID, BE READY and BE SURE at week 16

	BE VIVID			BE READY		BE SURE	
	Placebo	Bimekizumab 320 mg Q4W	Ustekinumab	Placebo	Bimekizumab 320 mg Q4W	Bimekizumab 320 mg Q4W	Adalimumab
Scalp IGA (N)^a	(72)	(285)	(146)	(74)	(310)	(296)	(138)
Scalp IGA 0/1, n (%)	11 (15.3)	240 (84.2) ^b	103 (70.5)	5 (6.8)	286 (92.3) ^b	256 (86.5)	93 (67.4)
pp-IGA (N)^a	(29)	(105)	(47)	(31)	(97)	(90)	(34)
pp-IGA 0/1, n (%)	7 (24.1)	85 (81.0)	39 (83.0)	10 (32.3)	91 (93.8)	75 (83.3)	24 (70.6)
mNAPSI 100 (N)^a	(51)	(194)	(109)	(50)	(210)	(181)	(95)
mNAPSI 100, n (%)	4 (7.8)	57 (29.4)	15 (13.8)	3 (6.0)	73 (34.8)	54 (29.8)	21 (22.1)

Bimekizumab 320 mg Q4W= bimekizumab every 4 weeks. Non responder imputation (NRI) is used.

Scalp IGA 0/1 and pp-IGA 0/1 responses were defined as Clear (0) or Almost Clear (1) with ≥ 2 category improvement relative to Baseline.

^a) Include only patients with a scalp Investigator Global Assessment (IGA) of 2 or greater, a palmoplantar IGA of 2 or greater and a modified Nail Psoriasis and Severity Index (mNAPSI) score > 0 at baseline.

^b) $p < 0.001$ versus placebo, adjusted for multiplicity

Scalp IGA and palmoplantar IGA responses in bimekizumab-treated patients were maintained through week 52 / 56. Nail psoriasis continued to improve beyond week 16. In BE VIVID, at week 52, 60.3% of patients treated with bimekizumab 320 mg every 4 weeks achieved complete nail clearance (mNAPSI 100). In BE READY, at week 56, 67.7% and 69.8% of week 16 PASI 90 responders achieved complete nail clearance with bimekizumab 320 mg every 8 weeks and bimekizumab 320 mg every 4 weeks respectively.

Maintenance of response

Table 4: Maintenance of responses with bimekizumab at week 52 in PASI100, PASI90, IGA 0/1 and Absolute PASI ≤ 2 responders at week 16*

PASI 100		PASI 90		IGA 0/1		Absolute PASI ≤ 2	
320mg Q4W (N=355)	320mg Q8W (N=182)	320mg Q4W (N=516)	320mg Q8W (N=237)	320mg Q4W (N=511)	320mg Q8W (N=234)	320mg Q4W (N=511)	320mg Q8W (N= 238)
n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
295 (83.1)	161 (88.5)	464 (89.9)	214 (90.3)	447 (87.5)	214 (91.5)	460 (90.0)	215 (90.3)

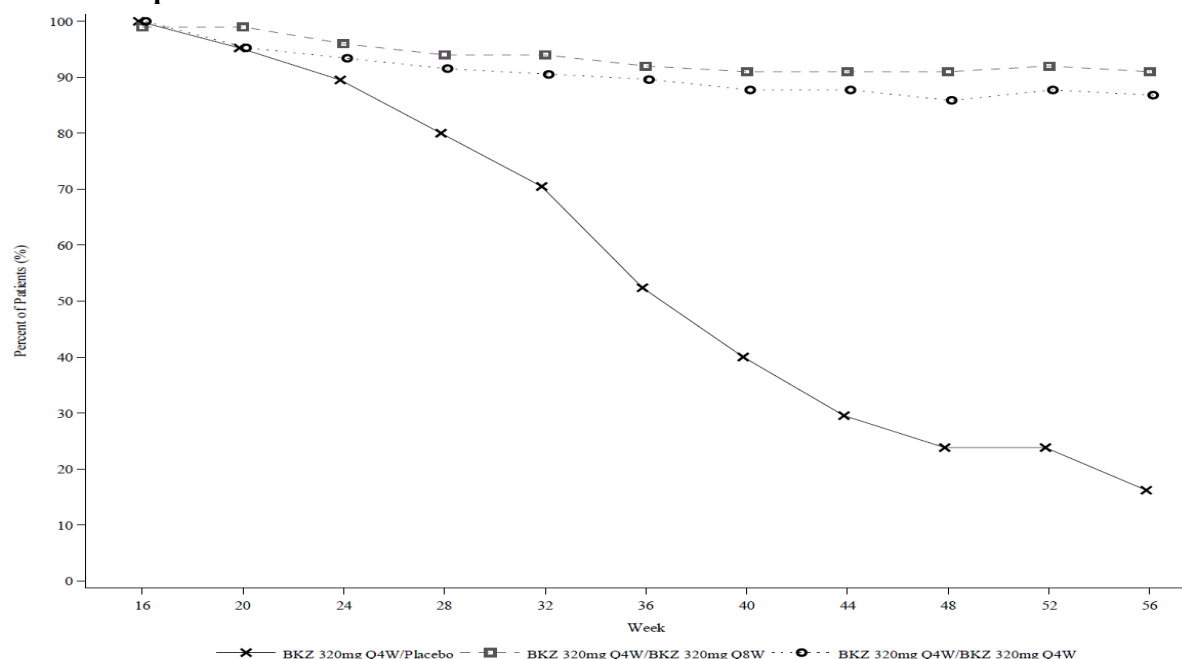
* Integrated analysis of BE VIVID, BE READY and BE SURE. NRI is used.

320 mg Q4W: bimekizumab 320 mg every 4 weeks followed by bimekizumab 320 mg every 4 weeks from week 16.

320 mg Q8W: bimekizumab 320 mg every 4 weeks followed by bimekizumab 320 mg every 8 weeks from week 16.

Durability of response (after bimekizumab discontinuation)

Figure 3: PASI 90 responder rates over time for PASI 90 responders at week 16 – Randomized withdrawal period in BE READY



NRI is used.

At week 16, 105 study participants started the Randomized-Withdrawal Period in the bimekizumab 320 mg Q4W/placebo group, 100 in the bimekizumab 320 mg Q4W/Q8W group, and 106 in the bimekizumab 320 mg Q4W/Q4W group.

In BE READY, for PASI 90 responders at week 16 who were re-randomised to placebo and withdrawn from bimekizumab, the median time to relapse, defined as loss of PASI 75, was approximately 28 weeks (32 weeks after the last bimekizumab dose). Among these patients, 88.1% regained a PASI 90 response within 12 weeks of restarting treatment with bimekizumab 320 mg every 4 weeks.

Health-related Quality of Life / Patient reported outcomes

Across all 3 studies, a greater proportion of patients treated with bimekizumab experienced no impact of psoriasis on their quality of life as measured by the Dermatology Life Quality Index (DLQI) compared to placebo and active comparator-treated patients at week 16 (Table 5).

Table 5: Quality of life in study BE VIVID, BE READY and BE SURE

	BE VIVID			BE READY		BE SURE	
	Placebo (N= 83) n (%)	Bimekizumab 320 mg Q4W (N= 321) n (%)	Ustekinumab (N= 163) n (%)	Placebo (N= 86) n (%)	Bimekizumab 320 mg Q4W (N= 349) n (%)	Bimekizumab 320 mg Q4W (N= 319) n (%)	Adalimumab (N= 159) n (%)
DLQI 0/1^a Baseline	3 (3.6)	16 (5.0)	5 (3.1)	4 (4.7)	11 (3.2)	10 (3.1)	13 (8.2)
DLQI 0/1^a Week 16	10 (12.0)	216 (67.3)	69 (42.3)	5 (5.8)	264 (75.6)	201 (63.0)	74 (46.5)

^{a)} DLQI absolute score of 0 or 1 indicates no impact of the disease on health-related quality of life. NRI is used.

DLQI 0/1 responses continued to increase beyond week 16 and then were maintained through week 52 / 56. In BE VIVID, DLQI 0/1 response rate at week 52 was 74.8% in patients treated with bimekizumab 320 mg every 4 weeks. In BE SURE at week 56, 78.9% and 74.1% of patients had a DLQI 0/1 with bimekizumab 320 mg every 8 weeks and bimekizumab 320 mg every 4 weeks, respectively.

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Bimzelx in one or more subsets of the paediatric population in psoriasis (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Absorption

Based on population pharmacokinetic analysis, following a single subcutaneous dose of 320 mg in plaque psoriasis patients, bimekizumab reached a median (2.5th and 97.5th percentile) peak plasma concentration of 25 (12 -50) µg/mL, between 3 and 4 days post dose.

Population pharmacokinetic analysis showed that bimekizumab was absorbed with an average absolute bioavailability of 70.1% in healthy volunteers.

Based on simulated data, the median (2.5th and 97.5th percentile) peak and trough concentration at steady-state following subcutaneous administration of 320 mg every 4 weeks are 43 (20-91) µg/mL and 20 (7-50) µg/mL respectively and steady-state is reached after approximately 16 weeks with every 4 weeks dosing regimen. Compared with exposure after a single dose, the population pharmacokinetic analysis showed that patients exhibited a 1.74-fold increase in peak plasma concentrations and area under the curve (AUC) following repeated four weekly dosing.

After switching from the 320 mg every 4 weeks dosing regimen to 320 mg every 8 weeks dosing regimen at week 16, steady-state is achieved approximately 16 weeks after the switch. Median (2.5th and 97.5th percentile) peak and trough plasma concentrations are 30 (14 -60) µg/mL and 5 (1-16) µg/mL respectively.

Distribution

Based on population pharmacokinetic analyses, the median (coefficient of variation %) volume of distribution (V/F) at steady state was 11.2 (30.5%) L in plaque psoriasis patients.

Biotransformation

Bimekizumab is a monoclonal antibody and is expected to be degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous immunoglobulins.

Elimination

Based on population pharmacokinetic analyses, the median (coefficient of variation %) apparent clearance (CL/F) of bimekizumab was 0.337 L/day (32.7%) and the mean terminal elimination half-life of bimekizumab was 23 days in clinical studies in patients with plaque psoriasis.

Linearity/non-linearity

Bimekizumab exhibited dose-proportional pharmacokinetics in patients with plaque psoriasis over a dose range from 64 mg to 480 mg following multiple subcutaneous administrations, with apparent clearance (CL/F) being independent of dose.

Pharmacokinetic/Pharmacodynamic relationship

A population pharmacokinetic/pharmacodynamic model was developed using all available data in moderate to severe plaque psoriasis patients. The analysis showed that higher bimekizumab concentrations are related to better Psoriasis Area and Severity Index (PASI) and Investigators Global Assessment (IGA) response. A dose of 320 mg every 4 weeks was shown to be an appropriate dose for

the initial treatment period and 320 mg every 8 weeks thereafter is appropriate for the maintenance period for the majority of moderate to severe plaque psoriasis patients (see Special Populations, Body weight).

Special populations

Body weight

Population pharmacokinetic modelling indicated that exposure decreased as body weight increased. The average plasma concentration in adult patients weighing ≥ 120 kg following a 320 mg subcutaneous injection was predicted to be at least 30% lower than in adult patients weighing 90 kg. Dose adjustment may be appropriate in some patients (see section 4.2).

Elderly

Based on population pharmacokinetic analysis with a limited number of elderly patients (n=110 for age ≥ 65 years and n= 14 for age ≥ 75 years), apparent clearance (CL/F) in elderly patients and patients less than 65 years of age was similar. No dose adjustment is required (see section 4.2).

Renal impairment or hepatic impairment

No specific studies have been conducted to determine the effect of renal or hepatic impairment on the pharmacokinetics of bimekizumab. The renal elimination of intact bimekizumab, an IgG monoclonal antibody, is expected to be low and of minor importance. Similarly, IgGs are mainly eliminated via intracellular catabolism and hepatic impairment is not expected to influence clearance of bimekizumab. Based on population pharmacokinetic analyses, hepatic function markers (ALT/bilirubin) did not have any impact on bimekizumab clearance in patients with plaque psoriasis.

Race

No clinically meaningful differences in bimekizumab exposure were observed in Japanese subjects compared to Caucasian subjects in a clinical pharmacokinetic study. No dose adjustment is required.

Gender

Population pharmacokinetic modelling indicated females may have 10% faster apparent clearance (CL/F) compared to males and it is not clinically meaningful. No dose adjustment is required.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on tissue cross-reactivity testing, repeat-dose toxicity studies (including safety pharmacology endpoints and assessment of fertility-related endpoints) and evaluation of pre- and postnatal development in the cynomolgus monkey.

In cynomolgus monkeys, bimekizumab-related effects were limited to mucocutaneous changes consistent with pharmacologic modulation of commensal microflora.

No mutagenicity or carcinogenicity studies were conducted with bimekizumab. However monoclonal antibodies are not expected to damage DNA or chromosomes. In a 26-week chronic toxicology study in cynomolgus monkeys there were no pre-neoplastic or neoplastic lesions observed at a dose resulting in 109 times the human exposure at 320 mg every 4 weeks.

In a peri- and postnatal development study in the cynomolgus monkey, bimekizumab showed no effects on gestation, parturition, infant survival, foetal and postnatal development when administered throughout organogenesis until parturition at a dose resulting in 27 times the human exposure at 320 mg every 4 weeks based on AUC. At birth, serum bimekizumab concentrations in infant monkeys were comparable to those of mothers.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycine
Sodium acetate trihydrate
Glacial acetic acid
Polysorbate 80
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Bimzelx 160 mg solution for injection in pre-filled syringe

Store in a refrigerator (2°C – 8°C).
Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

The pre-filled syringe may be stored at room temperature (up to 25°C) for a single period of maximum 25 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 25 days or by the expiry date printed on the container, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

Bimzelx 160 mg solution for injection in pre-filled pen

Store in a refrigerator (2°C – 8°C).
Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

The pre-filled pen may be stored at room temperature (up to 25°C) for a single period of maximum 25 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 25 days or by the expiry date printed on the container, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.

6.5 Nature and contents of container

Bimzelx 160 mg solution for injection in pre-filled syringe

One mL pre-filled syringe (type I glass) with a fluoropolymer-laminated bromobutyl rubber stopper, staked 27G, ½” thin wall needle, and a polypropylene rigid needle shield assembled in a passive safety device.

Pack size of 1 pre-filled syringe.

Pack size of 2 pre-filled syringes.

Multipack containing 3 (3 packs of 1) pre-filled syringes.

Multipack containing 4 (2 packs of 2) pre-filled syringes.

Not all pack sizes may be marketed.

Bimzelx 160 mg solution for injection in pre-filled pen

One mL pre-filled pen containing a pre-filled syringe (type I glass) with a fluoropolymer-laminated bromobutyl rubber stopper, staked 27G, ½” thin wall needle, and a polypropylene rigid needle shield.

Pack size of 1 pre-filled pen.

Pack size of 2 pre-filled pens.

Multipack containing 3 (3 packs of 1) pre-filled pens.

Multipack containing 4 (2 packs of 2) pre-filled pens.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

UCB Pharma S.A.
Allée de la Recherche 60
B-1070 Bruxelles
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

Bimzelx 160 mg solution for injection in pre-filled syringe

EU/1/21/1575/001

EU/1/21/1575/002

EU/1/21/1575/003

EU/1/21/1575/004

Bimzelx 160 mg solution for injection in pre-filled pen

EU/1/21/1575/005

EU/1/21/1575/006

EU/1/21/1575/007

EU/1/21/1575/008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

ANNEX II

- A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Rentschler Biopharma SE
Erwin-Rentschler-Strasse 21
88471 Laupheim
Germany

Name and address of the manufacturer(s) responsible for batch release

UCB Pharma S.A.
Chemin du Foriest
1420 Braine-l'Alleud
Belgium

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

PRE-FILLED SYRINGE CARTON

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled syringe
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled syringe contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
1 pre-filled syringe
2 pre-filled syringes

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.
Do not shake.
Two pre-filled syringes are needed to administer a full dose.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

May be stored at room temperature (up to 25°C) for a maximum of 25 days.

Keep the pre-filled syringe in the outer carton to protect from light.

Keep the pre-filled syringes in the outer carton to protect from light.

Date removed from refrigerator:

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

UCB Pharma S.A. (logo)

Allée de la Recherche 60

B-1070 Bruxelles

Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/001 Pack containing 1 pre-filled syringe

EU/1/21/1575/002 Pack containing 2 pre-filled syringes

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON OF PRE FILLED SYRINGE MULTIPACK (WITH BLUEBOX)

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled syringe
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled syringe contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multipack: 3 (3 packs of 1) pre-filled syringes

Multipack: 4 (2 packs of 2) pre-filled syringes

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Subcutaneous use

Do not shake.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
May be stored at room temperature (up to 25°C) for a maximum of 25 days.
Keep the pre-filled syringes in the outer carton to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

UCB Pharma S.A. (logo)
Allée de la Recherche 60
B-1070 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/003 3 pre-filled syringes (3 packs of 1)
EU/1/21/1575/004 4 pre-filled syringes (2 packs of 2)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON OF PRE FILLED SYRINGE MULTIPACK (WITHOUT BLUEBOX)

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled syringe
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled syringe contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 pre-filled syringe

2 pre-filled syringes

Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use

Read the package leaflet before use.

Do not shake.

Two pre-filled syringes are needed to administer a full dose.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

May be stored at room temperature (up to 25°C) for a maximum of 25 days.

Keep the pre-filled syringe in the outer carton to protect from light.

Keep the pre-filled syringes in the outer carton to protect from light.

Date removed from refrigerator:

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

UCB Pharma S.A. (logo)

Allée de la Recherche 60

B-1070 Bruxelles

Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/003 3 pre-filled syringes (3 packs of 1)

EU/1/21/1575/004 4 pre-filled syringes (2 packs of 2)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
PRE-FILLED SYRINGE LABEL**

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Bimzelx 160 mg injection
bimekizumab
SC

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 mL

6. OTHER

UCB Pharma S.A. (logo)

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

PRE-FILLED PEN CARTON

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled pen
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled pen contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
1 pre-filled pen
2 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.
Do not shake.
Two pre-filled pens are needed to administer a full dose.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

May be stored at room temperature (up to 25°C) for a maximum of 25 days.

Keep the pre-filled pen in the outer carton to protect from light.

Keep the pre-filled pens in the outer carton to protect from light.

Date removed from refrigerator:

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UCB Pharma S.A. (logo)

Allée de la Recherche 60

B-1070 Bruxelles

Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/005 Pack containing 1 pre-filled pen

EU/1/21/1575/006 Pack containing 2 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON OF PRE FILLED PEN MULTIPACK (WITH BLUEBOX)

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled pen
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled pen contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multipack: 3 (3 packs of 1) pre-filled pens

Multipack: 4 (2 packs of 2) pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use

Read the package leaflet before use.

Do not shake.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
May be stored at room temperature (up to 25°C) for a maximum of 25 days.
Keep the pre-filled pens in the outer carton to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

UCB Pharma S.A. (logo)
Allée de la Recherche 60
B-1070 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/007 3 pre-filled pens (3 packs of 1)
EU/1/21/1575/008 4 pre-filled pens (2 packs of 2)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON OF PRE FILLED PEN MULTIPACK (WITHOUT BLUEBOX)

1. NAME OF THE MEDICINAL PRODUCT

Bimzelx 160 mg solution for injection in pre-filled pen
bimekizumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled pen contains 160 mg bimekizumab in one mL.

3. LIST OF EXCIPIENTS

Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 pre-filled pen

2 pre-filled pens

Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use

Read the package leaflet before use.

Do not shake.

Two pre-filled pens are needed to administer a full dose.

Lift here to open.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

May be stored at room temperature (up to 25°C) for a maximum of 25 days.

Keep the pre-filled pen in the outer carton to protect from light.

Keep the pre-filled pens in the outer carton to protect from light.

Date removed from refrigerator:

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

UCB Pharma S.A. (logo)

Allée de la Recherche 60

B-1070 Bruxelles

Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/21/1575/007 3 pre-filled pens (3 packs of 1)

EU/1/21/1575/008 4 pre-filled pens (2 packs of 2)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Bimzelx 160 mg

17. UNIQUE IDENTIFIER – 2D BARCODE**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
PRE-FILLED PEN LABEL**

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Bimzelx 160 mg injection
bimekizumab
SC

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 mL

6. OTHER

UCB Pharma S.A. (logo)

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Bimzelx 160 mg solution for injection in pre-filled syringe bimekizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bimzelx is and what it is used for
 2. What you need to know before you use Bimzelx
 3. How to use Bimzelx
 4. Possible side effects
 5. How to store Bimzelx
 6. Contents of the pack and other information
- Instructions for use

1. What Bimzelx is and what it is used for

What Bimzelx is

Bimzelx contains the active substance bimekizumab.

What Bimzelx is used for

Bimzelx is used in adults to treat a skin condition called plaque psoriasis. Bimzelx reduces the symptoms, including pain, itching, and scaling of the skin.

How Bimzelx works

Bimekizumab, the active substance in Bimzelx, belongs to a group of medicines called interleukin (IL) inhibitors. Bimekizumab works by reducing the activity of two proteins called IL-17A and IL-17F, which are involved in causing inflammation. There are higher levels of these proteins in inflammatory diseases such as psoriasis.

2. What you need to know before you use Bimzelx

Do not use Bimzelx

- if you are allergic to bimekizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including tuberculosis (TB), which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Bimzelx if:

- you have an infection or an infection that keeps coming back.
- you recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Bimzelx.
- you have ever had tuberculosis (TB).
- you have ever had inflammatory bowel disease (Crohn's disease or ulcerative colitis).

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using Bimzelx and tell your doctor or get medical help immediately if you notice blood in the stool, abdominal cramps, pain, diarrhoea or weight loss. These may be signs of new or worsening inflammatory bowel disease (Crohn's disease or ulcerative colitis).

Look out for infections and allergic reactions

Bimzelx can rarely cause serious infections. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious infection. Such signs are listed under "Serious side effects" in section 4.

Bimzelx can potentially cause serious allergic reactions. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious allergic reaction. Such signs may include:

- difficulty breathing or swallowing
- low blood pressure, which can make you dizzy or light-headed
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Children and adolescents

Do not give this medicine to children and young people under 18 years of age. This is because it has not been studied in this age group.

Other medicines and Bimzelx

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Bimzelx in pregnancy. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 17 weeks after your last dose of Bimzelx.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you can breast-feed or use Bimzelx.

Driving and using machines

Bimzelx is unlikely to affect your ability to drive and use machines.

Bimzelx contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially "sodium free".

3. How to use Bimzelx

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Bimzelx is given and for how long

The recommended dose, given as injections under your skin ('subcutaneous injections') is as follows:

- 320 mg (given as **two** pre-filled syringes, containing 160 mg each) at weeks 0, 4, 8, 12, 16.
- From week 16, you will use 320 mg (**two** pre-filled syringes, containing 160 mg each) every 8 weeks. If you weigh more than 120 kg, your doctor may decide to continue your injections every 4 weeks from week 16.

You and your doctor or nurse will decide if you should inject this medicine yourself. Do not inject this medicine unless you have been trained by a healthcare professional. A caregiver may also give your injections after they have been trained.

Read the '**Instructions for use**' at the end of this leaflet before injecting Bimzelx pre-filled syringe yourself.

If you use more Bimzelx than you should

Tell your doctor if you have used more Bimzelx than you should or if you have injected your dose earlier than you should.

If you forget to use Bimzelx

Talk to your doctor if you have forgotten to inject a dose of Bimzelx.

If you stop using Bimzelx

Talk to your doctor before you stop using Bimzelx. If you stop treatment, your psoriasis symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or get medical help **immediately** if you get any of the following side effects:

Possible serious infection - the signs may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using Bimzelx.

Other side effects

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common (may affect more than 1 in 10 people)

- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common (may affect up to 1 in 10 people)

- thrush in the mouth or throat with symptoms such as white or yellow patches; red or sore mouth and pain with swallowing
- fungal infection of the skin, such as athlete's foot between the toes
- ear infections
- cold sores (herpes simplex infections)
- stomach flu (gastroenteritis)
- inflamed hair follicles which may look like pimples
- headache
- itchy, dry skin or an eczema-like rash sometimes with swollen and reddened skin (dermatitis)
- acne
- redness, pain or swelling at the site of injection
- feeling tired

Uncommon (may affect up to 1 in 100 people)

- lowered levels of white blood cells (neutropenia)
- fungal infections of the skin and mucous membranes (including oesophageal candidiasis)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- blood in the stool, abdominal cramps and pain, diarrhoea or weight loss (signs of bowel problems)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bimzelx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator between 2°C and 8°C. Do not freeze.

Keep the pre-filled syringes in the original carton in order to protect from light.

Bimzelx can be kept out of the refrigerator for up to 25 days. This must be in the outer carton, not above 25°C and away from direct light. Do not use the pre-filled syringes after this time period. There is a space on the box so you can write the date it was taken out of the refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bimzelx contains

- The active substance is bimekizumab. Each pre-filled syringe contains 160 mg of bimekizumab in the 1 mL solution.
- The other ingredients are glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80 and water for injections.

What Bimzelx looks like and contents of the pack

Bimzelx is a clear to slightly opalescent and pale brownish-yellow liquid. It comes in a single use disposable pre-filled syringe with needle cap.

Bimzelx is available in unit packs containing 1 or 2 pre-filled syringe(s) and in multipacks comprising 3 cartons, each containing 1 pre-filled syringe, or in multipacks comprising 2 cartons, each containing 2 pre-filled syringes.

Not all pack sizes may be marketed.

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Manufacturer

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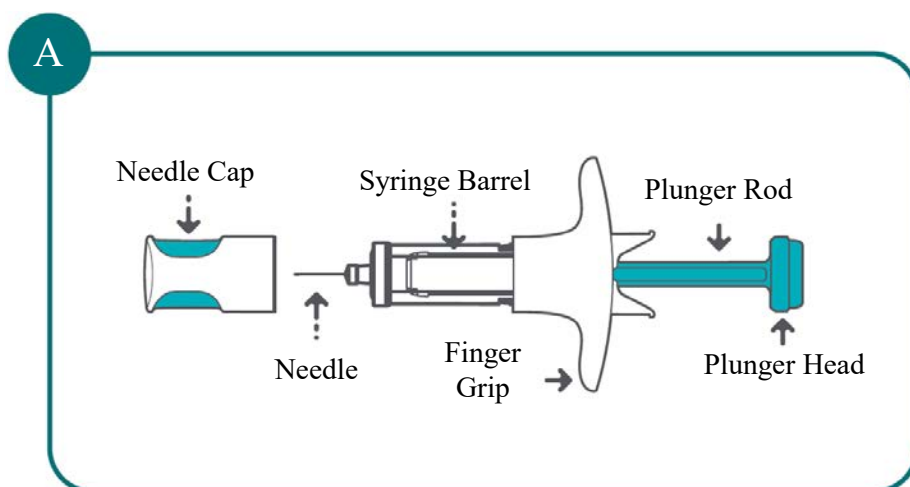
Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>

Instructions for use

Read all the instructions below before you use Bimzelx pre-filled syringe.

Bimzelx pre-filled syringe at a glance (see Figure A):



Important information:

- Your healthcare professional should show you how to prepare and inject Bimzelx using the pre-filled syringe. **Do not** inject yourself or someone else until you have been shown how to inject Bimzelx the right way.
- You and/or your caregiver should read these Instructions for Use before each use of Bimzelx.
- Call your healthcare professional if you or your caregiver have any questions about how to inject Bimzelx the right way.
- **To receive your full dose, you will need to use 2 Bimzelx pre-filled syringes, one after the other.**
- The Bimzelx pre-filled syringe has a needle safety feature. This will cover the needle automatically after the injection is finished. The needle safety feature will help to prevent needle injury to anyone who handles the pre-filled syringe after injection.

Do not use this medicine and return it to the pharmacy if:

- the expiry date (EXP) has passed.
- the carton seal is broken.
- the pre-filled syringe has been dropped or looks damaged.
- the liquid has ever been frozen (even if thawed).

For a more comfortable injection: Take the Bimzelx pre-filled syringes out of the refrigerator and let them sit on a flat surface at room temperature for **30 to 45 minutes** before injecting.

- Do not warm in any other way, such as in a microwave or in hot water.
- Do not shake the pre-filled syringes.
- Do not uncup the pre-filled syringes until you are ready to inject.

Follow the steps below each time you use Bimzelx.

Step 1: Setting up for your injections

Place the following items on a clean flat, well-lit work surface, like a table:

- 2 Bimzelx pre-filled syringes

You will also need (not included in the carton):

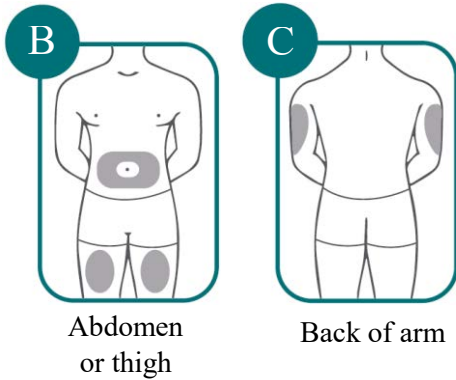
- 2 alcohol wipes
- 2 clean cotton balls
- 1 sharps disposal container. See “Throw away the used Bimzelx pre-filled syringe” at the end of these Instructions for Use.

Start with one pre-filled syringe for the first injection.

For the full dose, you need 2 injections, one after the other.

Step 2: Choose injection site and prepare your injection**2a: Choose your injection site**

- The places you may choose for your injection are:
 - your stomach (abdomen) or your thigh (**see Figure B**).
 - the back of your arm may also be used if a caregiver is giving you the injection (**see Figure C**).



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly-button (navel).
- You should use a different place for each injection. Do not use the same place to inject twice in a row.

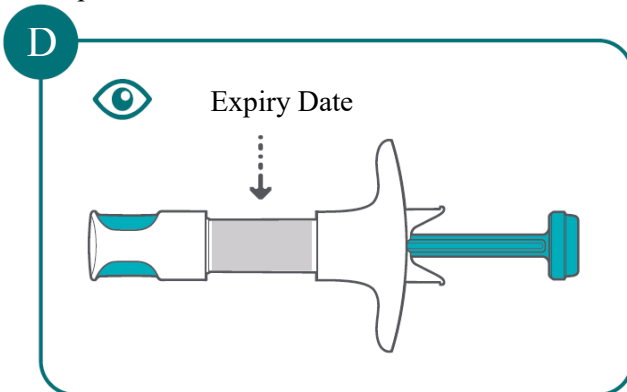
2b: Wash your hands well with soap and water and dry with a clean towel

2c: Prepare your skin

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

2d: Check the pre-filled syringe (see Figure D)

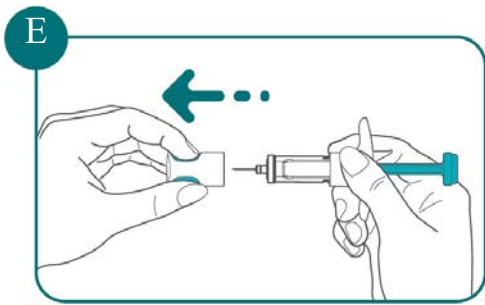
- Make sure the name Bimzelx and expiry date appear on the label.
- Check the medicine through the viewing window. The medicine should be pale brownish-yellow and free of particles. You may see air bubbles in the liquid. This is normal.
- Do not use the Bimzelx pre-filled syringe if the medicine is cloudy, discoloured, or has particles.



Step 3: Inject Bimzelx

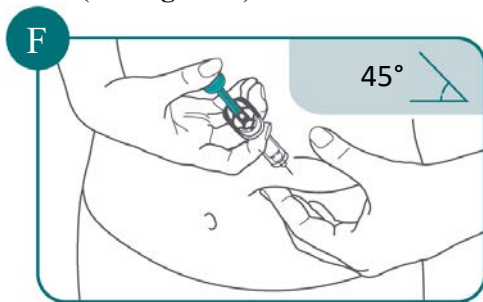
3a: Remove the pre-filled syringe needle cap

- Hold the pre-filled syringe around the finger grip with one hand. Pull the cap straight off the pre-filled syringe with the other hand (see Figure E). You may see a drop of liquid on the tip of the needle, this is normal.
 - **Do not** touch the needle or let the needle touch any surface.
 - **Do not** hold the plunger rod when you remove the cap. If you accidentally remove the plunger rod, throw the pre-filled syringe in the sharps disposal container and get a new one.
 - **Do not** put the needle cap back on. If you do, you could damage the needle or prick yourself by accident.

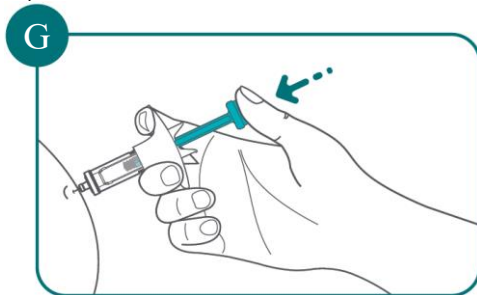


3b: Gently pinch and hold with one hand a fold of skin that you cleaned for the injection. With the other hand, insert the needle into your skin at about 45 degree angle

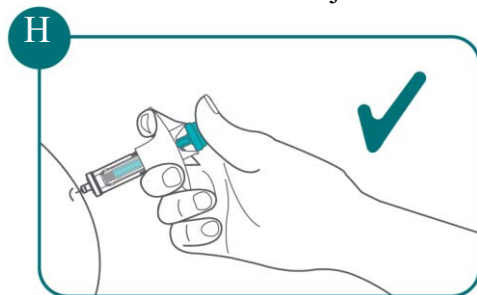
- Push the needle all the way in. Then gently let go of your skin. Make sure the needle is in place (see Figure F).



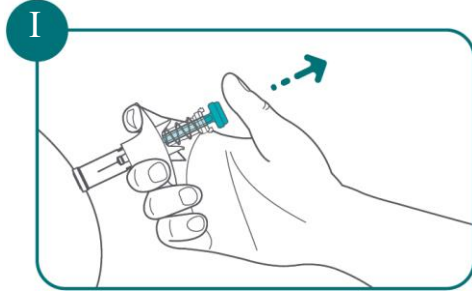
3c: Firmly push the plunger head all the way down until all the medicine is injected (see Figure G)



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



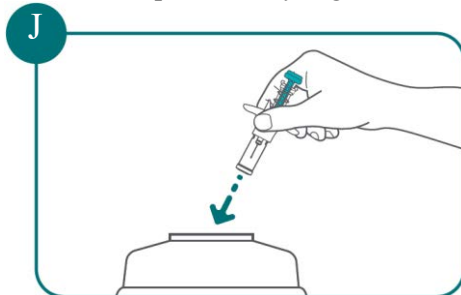
3d: Lift your thumb off the plunger head (see Figure I). The needle will automatically move back in and lock in place



- Press a dry 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 plaster, if needed.

Step 4: Throw away the used Bimzelx pre-filled syringe

Put the used pre-filled syringe in a sharps disposal container straight away after use (see **Figure J**).



For the second injection of your prescribed dose, use a new Bimzelx pre-filled syringe and repeat steps 2 to 4.

Make sure to select a new injection site for your second injection.

Package leaflet: Information for the user

Bimzelx 160 mg solution for injection in pre-filled pen bimekizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bimzelx is and what it is used for
 2. What you need to know before you use Bimzelx
 3. How to use Bimzelx
 4. Possible side effects
 5. How to store Bimzelx
 6. Contents of the pack and other information
- Instructions for use

1. What Bimzelx is and what it is used for

What Bimzelx is

Bimzelx contains the active substance bimekizumab.

What Bimzelx is used for

Bimzelx is used in adults to treat a skin condition called plaque psoriasis. Bimzelx reduces the symptoms, including pain, itching, and scaling of the skin.

How Bimzelx works

Bimekizumab, the active substance in Bimzelx, belongs to a group of medicines called interleukin (IL) inhibitors. Bimekizumab works by reducing the activity of two proteins called IL-17A and IL-17F, which are involved in causing inflammation. There are higher levels of these proteins in inflammatory diseases such as psoriasis.

2. What you need to know before you use Bimzelx

Do not use Bimzelx

- if you are allergic to bimekizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including tuberculosis (TB), which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Bimzelx if:

- you have an infection or an infection that keeps coming back.
- you recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Bimzelx.
- you have ever had tuberculosis (TB).
- you have ever had inflammatory bowel disease (Crohn's disease or ulcerative colitis).

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using Bimzelx and tell your doctor or get medical help immediately if you notice blood in the stool, abdominal cramps, pain, diarrhoea or weight loss. These may be signs of new or worsening inflammatory bowel disease (Crohn's disease or ulcerative colitis).

Look out for infections and allergic reactions

Bimzelx can rarely cause serious infections. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious infection. Such signs are listed under "Serious side effects" in section 4.

Bimzelx can potentially cause serious allergic reactions. Talk to your doctor or get medical help **immediately** if you notice any signs of a serious allergic reaction. Such signs may include:

- difficulty breathing or swallowing
- low blood pressure, which can make you dizzy or light-headed
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Children and adolescents

Do not give this medicine to children and young people under 18 years of age. This is because it has not been studied in this age group.

Other medicines and Bimzelx

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Bimzelx in pregnancy. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 17 weeks after your last dose of Bimzelx.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you can breast-feed or use Bimzelx.

Driving and using machines

Bimzelx is unlikely to affect your ability to drive and use machines.

Bimzelx contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially "sodium free".

3. How to use Bimzelx

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Bimzelx is given and for how long

The recommended dose, given as injections under your skin ('subcutaneous injections') is as follows:

- 320 mg (given as **two** pre-filled pens, containing 160 mg each) at weeks 0, 4, 8, 12, 16.
- From week 16, you will use 320 mg (**two** pre-filled pens, containing 160 mg each) every 8 weeks. If you weigh more than 120 kg, your doctor may decide to continue your injections every 4 weeks from week 16.

You and your doctor or nurse will decide if you should inject this medicine yourself. Do not inject this medicine unless you have been trained by a healthcare professional. A caregiver may also give your injections after they have been trained.

Read the '**Instructions for use**' at the end of this leaflet before injecting Bimzelx pre-filled pen yourself.

If you use more Bimzelx than you should

Tell your doctor if you have used more Bimzelx than you should or if you have injected your dose earlier than you should.

If you forget to use Bimzelx

Talk to your doctor if you have forgotten to inject a dose of Bimzelx.

If you stop using Bimzelx

Talk to your doctor before you stop using Bimzelx. If you stop treatment, your psoriasis symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or get medical help **immediately** if you get any of the following side effects:

Possible serious infection - the signs may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using Bimzelx.

Other side effects

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common (may affect more than 1 in 10 people)

- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common (may affect up to 1 in 10 people)

- thrush in the mouth or throat with symptoms such as white or yellow patches; red or sore mouth and pain with swallowing
- fungal infection of the skin, such as athlete's foot between the toes
- ear infections
- cold sores (herpes simplex infections)
- stomach flu (gastroenteritis)
- inflamed hair follicles which may look like pimples
- headache
- itchy, dry skin or an eczema-like rash sometimes with swollen and reddened skin (dermatitis)
- acne
- redness, pain or swelling at the site of injection
- feeling tired

Uncommon (may affect up to 1 in 100 people)

- lowered levels of white blood cells (neutropenia)
- fungal infections of the skin and mucous membranes (including oesophageal candidiasis)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
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Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bimzelx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator between 2°C and 8°C. Do not freeze.

Keep the pre-filled pens in the original carton in order to protect from light.

Bimzelx can be kept out of the refrigerator for up to 25 days. This must be in the outer carton, not above 25°C and away from direct light. Do not use the pre-filled pens after this time period. There is a space on the box so you can write the date it was taken out of the refrigerator.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bimzelx contains

- The active substance is bimekizumab. Each pre-filled pen contains 160 mg of bimekizumab in the 1 mL solution.
- The other ingredients are glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80 and water for injections.

What Bimzelx looks like and contents of the pack

Bimzelx is a clear to slightly opalescent and pale brownish-yellow liquid. It comes in a single use disposable pre-filled pen.

Bimzelx is available in unit packs containing 1 or 2 pre-filled pen(s) and in multipacks comprising 3 cartons, each containing 1 pre-filled pen, or in multipacks comprising 2 cartons, each containing 2 pre-filled pens.

Not all pack sizes may be marketed.

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This leaflet was last revised in .

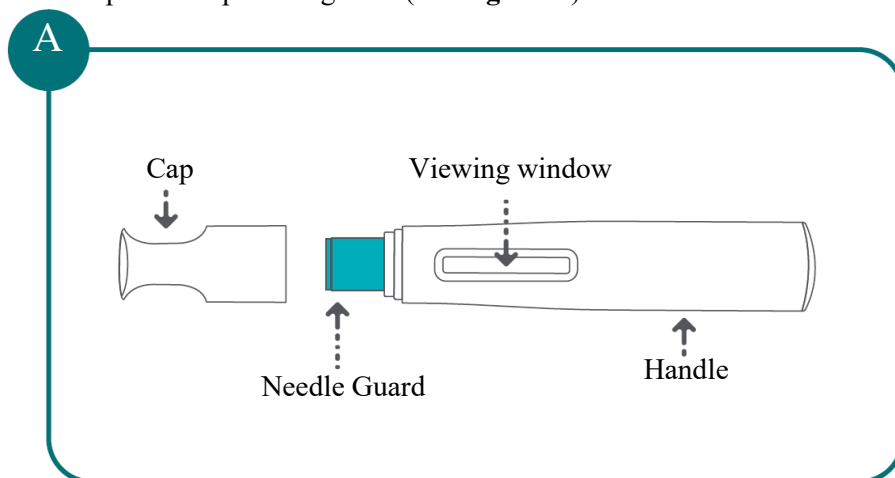
Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

Instructions for use

Read all the instructions below before you use Bimzelx pre-filled pen.

Bimzelx pre-filled pen at a glance (see **Figure A**):



Important information:

- Your healthcare professional should show you how to prepare and inject Bimzelx using the pre-filled pen. **Do not** inject yourself or someone else until you have been shown how to inject Bimzelx the right way.
- You and/or your caregiver should read these Instructions for Use before each use of Bimzelx.
- Call your healthcare professional if you or your caregiver have any questions about how to inject Bimzelx the right way.
- **To receive your full dose, you will need to use 2 Bimzelx pre-filled pens, one after the other.**

Do not use this medicine and return it to the pharmacy if:

- the expiry date (EXP) has passed.
- the carton seal is broken.
- the pre-filled pen has been dropped or looks damaged.
- the liquid has ever been frozen (even if thawed).

For a more comfortable injection: Take the Bimzelx pre-filled pens out of the refrigerator and let them sit on a flat surface at room temperature for **30 to 45 minutes** before injecting.

- Do not warm in any other way, such as in a microwave or in hot water.
- Do not shake the pre-filled pens.
- Do not uncap the pre-filled pens until you are ready to inject.

Follow the steps below each time you use Bimzelx.

Step 1: Setting up for your injections

Place the following items on a clean flat, well-lit work surface, like a table:

- 2 Bimzelx pre-filled pens

You will also need (not included in the carton):

- 2 alcohol wipes
- 2 clean cotton balls
- 1 sharps disposal container. See “Throw away the used Bimzelx pre-filled pen” at the end of these Instructions for Use.

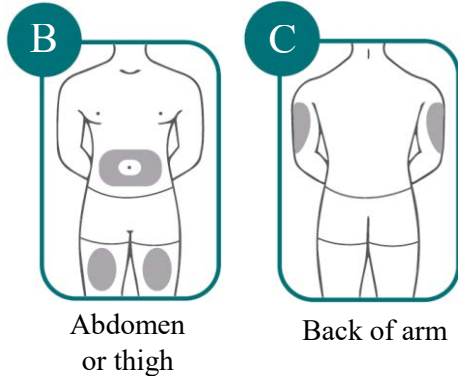
Start with one pre-filled pen for the first injection.

For the full dose, you need 2 injections, one after the other.

Step 2: Choose injection site and prepare your injection

2a: Choose your injection site

- The places you may choose for your injection are:
 - your stomach (abdomen) or your thigh (see **Figure B**).
 - the back of your arm may also be used if a caregiver is giving you the injection (see **Figure C**).



- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or areas with scars or stretch marks.
- Do not inject within 5 cm of the belly-button (navel).
- You should use a different place for each injection. Do not use the same place to inject twice in a row.

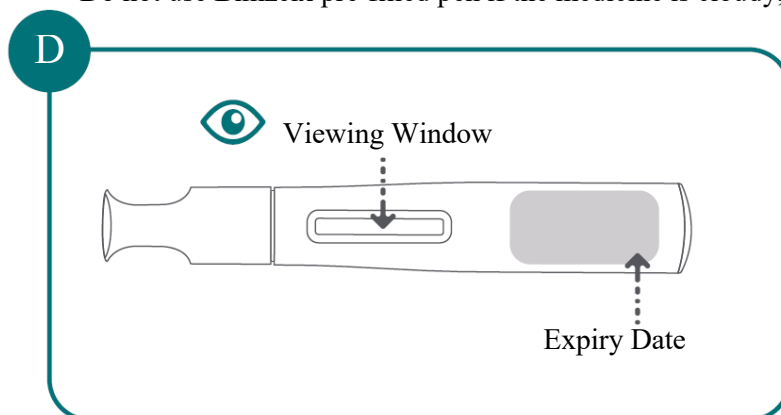
2b: Wash your hands well with soap and water and dry with a clean towel

2c: Prepare your skin

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

2d: Check the pre-filled pen (see Figure D)

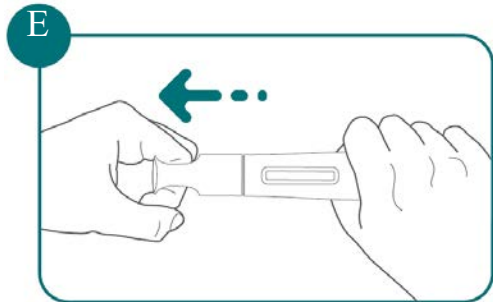
- Make sure the name Bimzelx and expiry date appear on the label.
- Check the medicine through the viewing window. The medicine should be pale brownish-yellow and free of particles. You may see air bubbles in the liquid. This is normal.
- Do not use Bimzelx pre-filled pen if the medicine is cloudy, discoloured, or has particles.



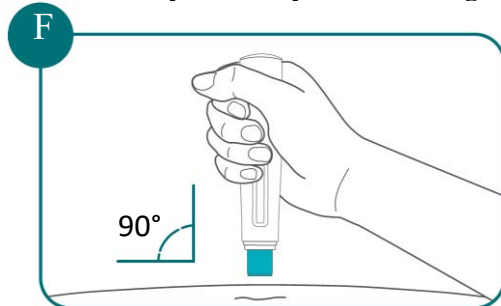
Step 3: Inject Bimzelx

3a: Remove the pre-filled pen cap

- Hold the pre-filled pen firmly with one hand around the handle. Pull the cap straight off the pre-filled pen with the other hand (see **Figure E**). Although you cannot see the needle tip, it is now uncovered.
- Do not touch the needle guard or put the cap back on. This is because it could activate the pre-filled pen and you could prick yourself.

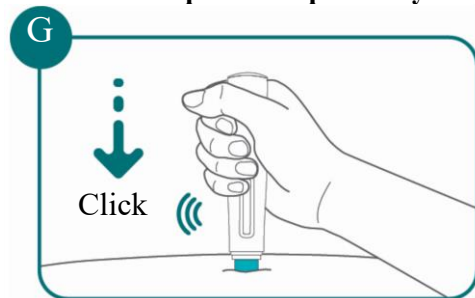


3b: Hold the pre-filled pen at a 90 degree angle to the cleaned injection site (see Figure F)



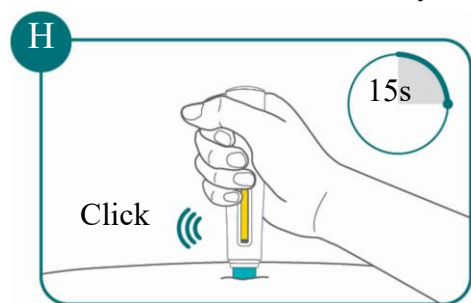
3c: Place the pre-filled pen flat against your skin, then firmly press the pre-filled pen down against your skin

You will hear a click sound. Your injection begins when the first “click” is heard (see **Figure G**).
Do not lift the pre-filled pen away from the skin.



3d: Keep holding the pre-filled pen in place and pressed firmly against your skin

- You will hear a second “click” within about 15 seconds after 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 colour indicator filling the viewing window (see **Figure H**).

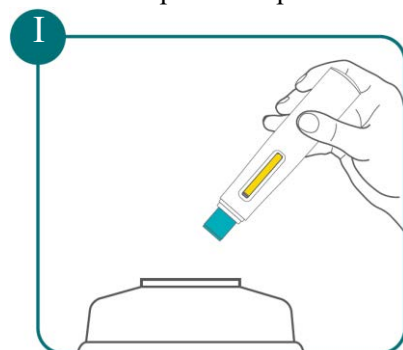


3e: Remove the pre-filled pen by carefully pulling it straight up from your skin. The needle guard will automatically cover the needle

- Press a dry 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 plaster, if needed.

Step 4: Throw away the used Bimzelx pre-filled pen

Put the used pre-filled pen in a sharps disposal container straight away after use (see **Figure I**).



For the second injection of your prescribed dose, use a new Bimzelx pre-filled pen, and repeat steps 2 to 4.

Make sure to select a new injection site for your second injection.