# Bimekizumab

## Instructions for use

***Table 1: Instructions for use (Bimekizumab)***

Pre-treatment

100 % Agreement [1]

- Physicians are encouraged to enrol their patients in a registry (if available)
- Objective assessment of disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI/Skindex-29 or -17)
- Medical history and physical examination including prior exposure to treatments, malignancies, infections, inflammatory bowel disease
- Recommended measures include:
    - Check for skin cancer
    - Check for lymphadenopathy
    - Laboratory parameters (see **Table 2**)
    - Exclusion of tuberculosis (see chapter: “tuberculosis”)
    - Check for evidence of active infection
    - Check need for vaccines
- Reliable contraception

During treatment

- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Laboratory controls (see **Table 2**)
- Medical history and physical examination focusing on infections (in particular upper respiratory tract infections, candida, tuberculosis), contraception and signs or symptoms of inflammatory bowel disease

Post-treatment

- After discontinuation of bimekizumab, patients should be followed up with medical history and physical examination
- For information regarding the ongoing need for contraception immediately following biologic treatment cessation, please see chapter: "Wish for child / pregnancy"

[1] due to personal-financial conflict of interest 4 abstentions

## Recommendations for lab controls

***Table 2: Recommended laboratory controls (Bimekizumab)***

| | | |
|---|---|---|
| **Parameter** | **Pre-treatment** | **After 3-6 months** |
| Full blood count | X | X |
| Liver enzymes | X | X |
| Serum creatinine | X | |
| Urine status | X | |
| Pregnancy test (urine or blood) | X | |
| CRP | X | |
| HBV/HCV | X | |
| HIV | X | |
| **Interferon gamma release assay (TB exclusion)** | x | |
| *Not all tests may be necessary for all patients. Patient history, risk exposure and patient characteristics have to be taken into account. Further specific testing may be required according to clinical signs, risk, and exposure.* | | |
| The recommendations are based on clinical experience. No evidence is available. | | |

## Adverse drug reactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Current evidence suggests a similar safety profile for bimekizumab compared to other IL-17 antagonists ixekizumab and secukinumab and IL-17R antagonist brodalumab. (In all phase III trials (BE READY, BE VIVID, BE SURE and BE RADIANT), bimekizumab was well tolerated. Recently, safety data

were pooled from a cohort of patients from 4 phase II randomized clinical trials (BE ABLE 1, BE ABLE 2, PS0016, and PS0018) and 4 phase III randomized clinical trials (BE VIVID, BE READY, BE SURE, and BE BRIGHT). In this analysis a total of 1789 patients (1252 [70.0%] men; mean [SD] age, 45.2 [13.5] years) were treated with 1 or more doses of bimekizumab. Total bimekizumab exposure was 3109.7 person-years. Treatment emergent adverse events (TEAEs) occurred at an exposure adjusted incidence rate (EAIR) of 202.4 per 100 person-years and did not increase with longer bimekizumab exposure. The 3 most frequently reported TEAEs were nasopharyngitis (19.1 per 100 person-years; 95% CI, 17.4-20.9 per 100 person-years), oral candidiasis (12.6 per 100 person-years; 95% CI, 11.3-14.0 per 100 person-years), and upper respiratory tract infection (8.9 per 100 person-years; 95% CI, 7.8-10.1 per 100 person-years). Most oral candidiasis events were mild or moderate; 3 events led to discontinuation. The EAIRs of inflammatory bowel disease (0.1 per 100 person-years; 95% CI, 0.0-0.3 per 100 person-years), adjudicated suicidal ideation and behaviour (0.0 per 100 person-years; 95% CI, 0.0-0.2 per 100 person-years), and adjudicated major adverse cardiac events (0.5 per 100 person-years; 95% CI, 0.3-0.8 per 100 person-years) were low. [1]

*Inflammatory Bowel Disease*

There is limited data in patients with IBD. Patients with a known history of Crohn's disease were excluded from phase III clinical trials. One case of ulcerative colitis was reported in a patient who received bimekizumab. Caution is advised in prescribing bimekizumab in patients with a history of IBD.

*Candidiasis*

In all phase III clinical trials [2-5], the majority of oral candidiasis cases were mild or moderate and no cases led to discontinuation. The incidence of bimekizumab oral candidiasis infections seems to be higher than observed with other IL-17 inhibitors [6]. The dual inhibition of IL-17A and IL-17F could impair more profoundly the normal mucocutaneous defense and, consequently, put at a greater risk of oral candidiasis. Early treatment of candida infections, either with topical or systemic treatment is recommended. For further information on treatment of candidiasis, see SmPC of antifungal drugs or international guidelines. [7,8] Cases are usually described as mild-to-moderate, respond to standard treatment and do not require bimekizumab treatment discontinuation. In case of recurrent infections, consider changing the antipsoriatic drug. Note that clinically significant, severe infections are always a contraindication for all biologics.

## Special consideration during treatment

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

*Surgery*

There is no data on the management of surgery in patients treated with bimekizumab. The decision to discontinue of bimekizumab prior to surgery must be based on individual factors, such as type and risk of surgical procedure, patient characteristics, severity of psoriasis in case of treatment discontinuation etc. Counselling with the surgeon is advised.

## Important contraindications

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

*Absolute contraindications:*

- Clinically important active infections

*Relative contraindications:*

- Pregnancy or breastfeeding
- Inflammatory bowel disease

## Drug interactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

No drug interactions expected. Combination therapy with other immunosuppressant agents has not been studied.

### Overdose/ measures in case of overdose

No cases of overdose have been reported. Doses of up to 320 mg have been administered in clinical studies. In case of overdose, the patient should be monitored and appropriate symptomatic treatment should be instituted immediately.

**References**

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