

# BILDYOS REMS

## FDA Required REMS Safety Information

Month YYYY

### Important Safety Update

Dear Healthcare Provider:

The FDA has required this safety update as part of the BILDYOS REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risk of BILDYOS**:

#### **Severe Hypocalcemia in Patients with Advanced Kidney Disease**

Patients with advanced chronic kidney disease (eGFR <30 mL/min/1.73 m<sup>2</sup>), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following BILDYOS administration.

- Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.
- To minimize the risk of hypocalcemia in patients with advanced chronic kidney disease (CKD):
  - Evaluate for the presence of chronic kidney disease-mineral bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25 (OH)<sub>2</sub> vitamin D prior to decisions regarding BILDYOS treatment.
  - Consider assessing bone turnover status (serum markers of bone turnover or bone biopsy) to evaluate the underlying bone disease that may be present.
  - Monitor serum calcium weekly for the first month after BILDYOS administration and monthly thereafter.
  - Coordinate care with healthcare providers with expertise in CKD-MBD for patients with advanced chronic kidney disease.

#### **Role of the Healthcare Provider**

- ✓ **Provide** each patient with a copy of the **Patient Guide**.
- ✓ **Review** information in the **Patient Guide** with each patient, including the serious risk of BILDYOS and the symptoms of severe hypocalcemia.
- ✓ **Advise** each patient to seek prompt medical attention if they have signs or symptoms of severe hypocalcemia.

**This letter does not contain the complete safety profile of BILDYOS. Please review the Prescribing Information enclosed. All BILDYOS REMS materials are also available at (BILDYOS REMS Website) or by contacting your local Organon Sales Representative.**

#### **Reporting Adverse Events**

To report Adverse Reactions with BILDYOS, please call representative of Shanghai Henlius Biotech, Inc. at 844-674-3200, or report the event at FDA MedWatch.

Sincerely,

Shanghai Henlius Biotech, Inc.