

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761392Orig1s000

761392Orig2s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

Ospomyv (denosumab-dssb) REMS

I. Administrative Information

Risk: Severe hypocalcemia

Application Number: BLA 761392 (and Unbranded Biological Product)

Application Holder: Samsung Bioepis Co., Ltd.

Initial REMS Approval: 02/2025

Most Recent REMS Update: 07/2025

II. REMS Goal

The goal of the Ospomyv REMS is to mitigate the risks of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), including dialysis-dependent patients, associated with Ospomyv.

Objective 1: Inform healthcare providers on:

- Risk of severe hypocalcemia in patients with advanced chronic kidney disease (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m²)
- Need to assess for presence of chronic kidney disease-mineral bone disorder (CKD-MBD) before initiating Ospomyv in patients with advanced chronic kidney disease.

III. REMS Requirements

To inform healthcare providers about the REMS and the risks and safe use of Ospomyv, Samsung Bioepis Co., Ltd. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plans
Healthcare providers who are likely to prescribe Ospomyv	REMS Letters: REMS Letter for Healthcare Providers, REMS Letter for Professional Societies with the quick response (QR) code and REMS Website link to the Prescribing Information. 1. Mail REMS Letter for Healthcare Providers within 60 calendar days of the date Ospomyv is first commercially distributed and again 12 months later. a. If returned, attempt to obtain updated address information and send a second letter by mail within 45 calendar days of the date the first letter is returned. If correct address cannot be obtained, the attempt will be documented. 2. Email REMS Letter for Professional Societies within 60 calendar days of the date Ospomyv is first commercially distributed and again 12 months later through the following professional societies and request the letter or content be provided to their members. If the first email is undeliverable, the REMS letter will be mailed within 30 calendar days. If the first email is marked as unopened, a second email will be sent within 7 calendar days. If the second email is undeliverable or marked as unopened, the REMS letter will be mailed within 30 calendar days:

	a. American Society of Bone Mineral Research b. American College of Rheumatology c. American Association of Clinical Endocrinologists d. Endocrine Society e. American Society of Clinical Oncology f. Bone Health and Osteoporosis Foundation g. North American Menopause Society h. American Academy of Family Physicians i. American College of Physicians 3. Make available via a link from the Ospomyv REMS Website. 4. Disseminate through field-based sales and/or medical representatives from the date Ospomyv is first commercially distributed for the duration of the REMS. 5. Disseminate and prominently display at Professional Meetings where Samsung Bioepis Co., Ltd. or representative has a Ospomyv commercial presence from the date Ospomyv is first commercially distributed for the duration of the REMS. Patient Guide and Prescribing Information 1. Disseminate and prominently display at Professional Meetings where Samsung Bioepis Co., Ltd. or representative has a Ospomyv commercial presence from the date Ospomyv is first commercially distributed for the duration of the REMS. 2. Disseminate through field-based sales and/or medical representatives during the initial and/or follow-up discussions with healthcare providers from the date Ospomyv is first commercially distributed for the duration of the REMS. Field-based sales and/or medical representatives to verbally review the risk messages contained in the Patient Guide and Prescribing Information during the visit with the healthcare provider. Website 1. Make the REMS website fully operational and all REMS materials available through the website by the date Ospomyv is first commercially distributed. 2. Maintain the REMS website from the date Ospomyv is first commercially distributed for the duration of the REMS. 3. Include a prominent REMS-specific link to the REMS website on all product websites for consumers and healthcare providers. The REMS website must not link back to the promotional product website(s).
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IV. REMS Assessment Timetable

Samsung Bioepis Co., Ltd. must submit REMS assessments at 18 months, 3 years, and 7 years from the date of initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Samsung Bioepis Co., Ltd. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Ospomyv REMS:

Training and Educational Material

Patient:

1. [Patient Guide](#)

Communication Materials

2. [REMS Letter for Healthcare Providers](#)
3. [REMS Letter for Professional Societies](#)

Other Materials

4. [REMS website](#)

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Communication Plan
2. Timetable for Submission of Assessments



Ospomyv™ (denosumab-dssb) 60 mg Pre-filled Syringe (PFS) Patient Guide

What is Ospomyv?

Ospomyv (denosumab-dssb) is a prescription medicine used to:

- Treat osteoporosis (thinning and weakening of bone) in women after menopause (“change of life”) who:
 - are at high risk for fracture (broken bone)
 - cannot use another osteoporosis medicine or other osteoporosis medicines did not work well
- Treat to increase bone mass in men with osteoporosis who are at high risk for fracture
- Treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body
- Treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body
- Treat osteoporosis in men and women who will be taking corticosteroid medicines (such as prednisone) for at least 6 months and are at high risk for fracture

What is the serious risk of Ospomyv?

Patients with advanced chronic kidney disease, including dialysis-dependent patients, are at risk of severe hypocalcemia (low calcium levels in your blood) following Ospomyv administration. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms which include:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Call your doctor right away if you think you may be having any of these symptoms.

What to expect before and during Ospomyv treatment:

- Talk to your doctor before starting Ospomyv.
- If you have low blood calcium before you start receiving Ospomyv, it may get worse during treatment.
- Your low blood calcium must be treated before you receive Ospomyv.
- Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take Ospomyv. Take calcium and vitamin D as your doctor tells you to.
- If you have advanced chronic kidney disease (may or may not be on kidney dialysis), Ospomyv may increase your risk for severe low calcium levels in your blood, leading to hospitalization, life-threatening events, and death.
- A mineral and bone disorder associated with kidney disease called chronic kidney disease-mineral bone disorder (CKD-MBD) may increase your risk for severe low calcium levels in blood. Before you start Ospomyv and during treatment, your doctor may need to do certain blood tests to check for CKD-MBD.

If you have advanced chronic kidney disease, your doctor may coordinate your Ospomyv treatment with a healthcare provider with expertise in CKD-MBD.

FDA-Required REMS Safety Information / Important Safety Notice

Month YYYY

Dear Healthcare Provider:

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

Severe Hypocalcemia in Patients with Advanced Kidney Disease

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m²), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following Ospomyv 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 and bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25 (OH)₂ vitamin D prior to decisions regarding Ospomyv 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 Ospomyv 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 a copy of the **Patient Guide**.
- ✓ **Review** information in the **Patient Guide** with your patients, including the serious risks of Ospomyv 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 for Ospomyv. Please review the Prescribing Information available at www.ospomyvrems.com. Prescribing information is also accessible by scanning the QR code below with your mobile phone. All Ospomyv REMS materials are also available at www.ospomyvrems.com.



Reporting Adverse Events

To report Adverse Reactions with Ospomyv, please call Samsung Bioepis Co., Ltd's designated point of contact at 1-833-267-3130, or report the event at FDA MedWatch.

Sincerely,

Samsung Bioepis Co., Ltd.

FDA-Required REMS Safety Information / Important Safety Notice

Month YYYY

Dear [Professional Society]:

The FDA has required Samsung Bioepis Co., Ltd. to distribute this safety notice to your organization as part of the Ospomyv REMS (Risk Evaluation and Mitigation Strategy). We request that you inform your members about the following **serious risk of Ospomyv**:

Severe Hypocalcemia in Patients with Advanced Kidney Disease

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m²), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following Ospomyv 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 and bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25 (OH)₂ vitamin D prior to decisions regarding Ospomyv 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 Ospomyv 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 a copy of the **Patient Guide**.
- ✓ **Review** information in the **Patient Guide** with your patients, including the serious risks of Ospomyv and the symptoms of severe hypocalcemia.
- ✓ **Advise** each patient to seek prompt medical attention if they have signs or symptoms of severe hypocalcemia.

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Sincerely,

Samsung Bioepis Co., Ltd.



Ospomyv™

Risk Evaluation and Mitigation Strategy

What is the Ospomyv REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration.

The purpose of the Ospomyv REMS is to inform healthcare providers and patients about the following serious risk of:

- Severe hypocalcemia in patients with advanced chronic kidney disease

The Ospomyv REMS program materials are designed to inform healthcare providers and their patients about the risk with Ospomyv. The Ospomyv REMS program materials include REMS Letter for Healthcare Providers and a Patient Guide. It is important that you discuss with each patient the information included in the Patient Guide.

To learn more about Ospomyv, read the [Important Safety Information](#) provided in this link and use the links on the right to access REMS supporting materials.

Resources

For Healthcare Providers:

 [REMS Letter for Healthcare Providers](#)

 [Prescribing Information](#)

 [Patient Guide](#)

For Patients:

 [Patient Guide](#)

Reporting Adverse Events

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with Ospomyv to Samsung Bioepis Co., Ltd, or its designee by phone at 1-833-267-3130 or to the FDA.



Ospomyv™

Risk Evaluation and Mitigation Strategy

Contact Us

If you have a question about the REMS, clinical inquiry or would like to report an adverse event related to Ospomyv, contact Samsung Bioepis Co., Ltd, or its designee by phone at 1-833-267-3130.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA E KEHOE
10/29/2025 11:16:08 AM

CHRISTY L OSGOOD
10/29/2025 12:56:36 PM