

PLEASE READ

**IMPORTANT MEDICINE
SAFETY INFORMATION**

APPROVED
BY THE



June 2025

**RE: Updates to the
Zeposia® (ozanimod)
additional risk
minimisation materials**

Dear Healthcare Professional,

The purpose of this letter is to inform you of updates made to the ozanimod additional risk minimisation materials (ARMM).

In line with changes made to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), the ozanimod ARMM have also been updated, as detailed below.

Prescriber's Checklist

- Cautionary wording has been added regarding immune reconstitution inflammatory syndrome (IRIS) in multiple sclerosis patients treated with S1P receptors modulators who developed progressive multifocal leukoencephalopathy (PML) and subsequently discontinued treatment with ozanimod.

Patient/Caregiver Guide

- The existing information on neurological signs and symptoms that a patient may experience during treatment with ozanimod has been expanded to include wording on IRIS.

Patient Card

- The title of this patient material [which is for women of childbearing potential (WCBP)] has been changed from 'Pregnancy-specific Patient Reminder Card' to 'Patient Card'.

In addition, the following updates have been made across all the three ozanimod ARMM:

- The requirement for additional monitoring has been removed for ozanimod. The black triangle symbol has therefore been deleted and the adverse event (AE) reporting information updated accordingly.
- In line with relevant pharmacovigilance legislation, a statement has been added on the front page of each material stating that "This risk minimisation material fulfils the conditions of the marketing authorisation for ozanimod and has been approved by the Health Products Regulatory Authority (HPRA)".
- Editorial amendments

2084-GB-2500019

Date of Preparation: April 2025

Approved by HPRA: June 2025

This is a non-promotional letter intended for Healthcare Professionals in Ireland only.

**Bristol-Myers Squibb
Pharmaceuticals uc**

Plaza 254
Blanchardstown Corporate Park 2
Dublin 15
D15 T867 Ireland
bms.com/ie

Office +353 (0)1 483 3625
Medical Information 1800 749 749
medical.information@bms.com

Directors:
Karen Costello
Barry Sexton
Annie Ong (Malaysian)

Registered In Ireland No: 15797. Registered Office: Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland

Hard copies of the updated ARMM are enclosed for your information.

Please discard any previous versions of the ozanimod ARMM that you may have.

Bristol Myers Squibb (BMS), in agreement with the Health Products Regulatory Authority (HPRA) and under the terms of the marketing authorisation, have agreed upon the following ARMM to help minimise the risks associated with the use of ozanimod:

- **Prescriber's Checklist**

This checklist includes information on the ozanimod treatment initiation criteria (including re-initiation); monitoring parameters prior to, during and after treatment with ozanimod, counselling points for patients and pregnancy prevention for WCBP.

- **Patient/Caregiver Guide**

This guide should be provided to patients, or caregivers of patients, receiving ozanimod as it provides important information including what patients need to be aware of before they start taking ozanimod, the signs and symptoms of important side effects they need to look out for during and after treatment and how to report side effects.

- **Patient Card**

This card should be provided to WCBP receiving ozanimod. It contains information on the potential risks if ozanimod is used during pregnancy, how to minimise these risks through pregnancy prevention and what the patient should do if they become pregnant while on treatment with ozanimod.

For full prescribing information, please refer to the ozanimod SmPC which can be found on www.medicines.ie (enter 'Zeposia' or 'ozanimod' in the 'Search' box, click on the required medicine, and then click on the 'SPC' tab) or www.hpra.ie (enter 'Zeposia' or 'ozanimod' in the 'Find a medicine' search box and click on 'EMA' next to any of the medicines that appear. Once the European Medicines Agency (EMA) page for Zeposia opens up, navigate to the 'Product Information' section on this page).

Reporting adverse events

Healthcare professionals are requested to continue reporting any suspected adverse drug reactions (ADRs) via HPRA Pharmacovigilance at www.hpra.ie.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.

Adverse events and pregnancies should also be reported to BMS Medical Information (Telephone: 1 800 749 749; E-mail: medical.information@bms.com).

Obtaining copies of the ozanimod ARMM

Electronic copies of the ozanimod ARMM can be viewed and/or downloaded via www.medicines.ie (enter 'Zeposia' or 'ozanimod' in the 'Search' box, click on the required medicine, and then click on the 'Ed Material' tabs) or www.hpra.ie (enter 'Zeposia' or 'ozanimod' in the 'Find a medicine' search box and click on 'EdM' next to any of the medicines that appear).

Hard copies of the educational materials can be ordered by contacting BMS Medical Information (Telephone: 1 800 749 749; E-mail: medical.information@bms.com).

Company Contact Point

Should you have any questions or require further information regarding the use of ozanimod, please contact BMS Medical Information (Telephone: 1 800 749 749; E-mail: medical.information@bms.com).

Sincerely,

Hartridge-Lambert,
Sidonie (00408945)

Digitally signed by Hartridge-Lambert, Sidonie (00408945)
DN: CN = Hartridge-Lambert, Sidonie (00408945)
email = Sidonie.Hartridge-Lambert@bms.com C = GB
O = Bristol-Myers Squibb Co. OU = BMS Users
Date: 2025.06.23 17:41:18 +01'00'

Sidonie Hartridge-Lambert
Medical Director UK & Ireland
Bristol-Myers Squibb Pharmaceuticals uc