ZEPOSIA® ozanimod

For more information, please refer to the Product Information
available at https://apps.medicines.org.au/files/cjpzepos.pdf
or contact BMS Medical Information on 1800 067 567
or Medinfo.australia@bms.com

Celgene | Bristol Myers Squibb™ Company

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

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Healthcare Professional Checklist

Important points to remember before, during, and after treatment

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TGA Approval Date of Patient Caregiver Guide: 19 January 2022
IMM-AU-2200011

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Patient Identification	Doctor Details
Name:	**Name:**
	Signature:
	Date:

TREATMENT INITIATION

Initiate treatment with a treatment initiation pack that lasts for 7 days. Start treatment with 230 micrograms once daily on Days 1–4, then increase the dose to 460 micrograms once daily on Days 5–7. Following the 7-day dose escalation, the maintenance dose is 920 micrograms once daily, starting on Day 8.

RE-INITIATION OF THERAPY FOLLOWING TREATMENT INTERRUPTION

The same dose escalation regimen described above is recommended when treatment is interrupted for:

- 1 day or more during the first 14 days of treatment
- More than 7 consecutive days between Day 15 and Day 28 of treatment
- More than 14 consecutive days after Day 28 of treatment

If the treatment interruption is of shorter duration than the above, continue treatment with the next dose as planned.

PRIOR TO TREATMENT INITIATION

- ☐ Obtain a baseline electrocardiogram (ECG) to determine whether any pre-existing cardiac abnormalities are present.
- ☐ Obtain recent (within last 6 months) liver function test results.
- ☐ Obtain recent (within last 6 months or after discontinuation of prior therapy) complete blood cell count (CBC, including lymphocyte count).
- ☐ Arrange an ophthalmological assessment in patients with risk factors for macular oedema, such as diabetes mellitus, history of uveitis or history of retinal disease.
  - ☐ I confirm that an ophthalmological assessment is not applicable for this patient.
- ☐ Confirm a negative pregnancy test result in women of childbearing potential prior to starting treatment (ZEPOSIA is Pregnancy Category D). Counsel women of childbearing potential to use effective contraception during treatment with ZEPOSIA and for at least 3 months following treatment discontinuation.
  - ☐ I confirm that a pregnancy test is not applicable to this patient.
- ☐ Delay treatment initiation in patients with any active infection until the infection is resolved.
- ☐ Check varicella zoster virus (VZV) antibody status in patients without a healthcare professional confirmed history of varicella or documentation of a full course of varicella vaccination. If negative, VZV vaccination is recommended at least 1 month prior to treatment initiation with ZEPOSIA.

- ☐ Consult a cardiologist to determine if ZEPOSIA can safely be initiated and to determine the most appropriate monitoring strategy, if treatment with ZEPOSIA is considered in patients with:
  - Significant QT interval prolongation (QTcF >450 msec in males, >470 msec in females)
  - Arrhythmias requiring Class Ia (e.g. quinidine, disopyramide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic medicinal products
  - ☐ I confirm that a cardiology consult is not applicable to this patient.

ZEPOSIA is contraindicated in patients with the following:

- Hypersensitivity to ozanimod or any of the excipients
- Experienced myocardial infarction (MI), unstable angina, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation or Class III/IV heart failure in the last 6 months
- History or presence of second-degree atrioventricular (AV) block Type II or third-degree AV block or sick sinus syndrome unless the patient has a functioning pacemaker
- Severe untreated sleep apnoea

☐ I confirm that none of these contraindications are applicable to this patient.

DURING TREATMENT AND AFTER TREATMENT

- ☐ Instruct patients to report symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine.
- ☐ Perform liver function tests in patients with symptoms suggestive of hepatic dysfunction. If significant liver injury is confirmed, ZEPOSIA should be discontinued.

  Patients with pre-existing liver disease may be at increased risk of developing elevated hepatic enzymes when taking ZEPOSIA.

- ☐ Instruct patients to report signs and symptoms of infections immediately to their doctor during and for up to 3 months after discontinuation of treatment with ZEPOSIA.
  - Consider interruption of treatment with ZEPOSIA if a patient develops a serious infection.
    - Avoid co-administration of anti-neoplastic, immunomodulatory, or non-corticosteroid immunosuppressive therapies due to the risk of additive immunosuppressive effects. When switching to ZEPOSIA from immunosuppressive medications, consider the duration of their effects and their mode of action to avoid unintended additive immunosuppressive effects.
  - Be vigilant for clinical symptoms including unexpected neurological or psychiatric symptoms or MRI findings that may be suggestive of progressive multifocal leukoencephalopathy (PML).
    - If PML is suspected a complete physical and neurological examination should be performed and withhold treatment with ZEPOSIA until PML has been excluded. If PML is confirmed, discontinue treatment with ZEPOSIA.
  - Avoid administration of live attenuated vaccines during and for 3 months after discontinuation of treatment with ZEPOSIA.

ZEPOSIA is Pregnancy Category D.

- ☐ Counsel women of childbearing potential about the serious potential risks of ZEPOSIA to the foetus.
- ☐ Counsel women of childbearing potential to use effective contraception during treatment with ZEPOSIA and for at least 3 months following treatment discontinuation.
- ☐ Counsel women of childbearing potential to stop ZEPOSIA at least 3 months before planning a pregnancy.
- ☐ While on treatment, women should not become pregnant. If a woman becomes pregnant while on treatment, consider discontinuing ZEPOSIA. Medical advice should be given regarding the risk of harmful effects to the foetus associated with ZEPOSIA treatment and ultrasonography examinations should be performed.
  - ☐ I confirm that counselling on pregnancy precautions is not applicable to this patient.

- ☐ Blood pressure should be regularly monitored during treatment with ZEPOSIA.

- ☐ Patients with a history of diabetes mellitus, uveitis or retinal disease should undergo an ophthalmological evaluation prior to treatment initiation with ZEPOSIA and have follow up evaluations while receiving therapy.
- ☐ Patients who present with visual symptoms of macular oedema should be evaluated and, if confirmed, treatment with ZEPOSIA should be discontinued.

Given the immunomodulatory/immunosuppressive properties of ZEPOSIA a potential risk for increased malignancy cannot be ruled out. Vigilance for basal cell carcinoma and other cutaneous neoplasms is recommended.

- ☐ Caution patients against exposure to sunlight without protection.
- ☐ Ensure patients are not receiving concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.

- ☐ Provide all patients/caregivers with the patient/caregiver guide.