ZEPOSIA® ▼ (ozanimod) Prescribing Information

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ZEPOSIA®▼(ozanimod) PRESCRIBING INFORMATION
Ireland

Consult Summary of Product Characteristics (SmPC) before prescribing.
▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

PRESENTATION: Hard capsule containing ozanimod 0.23 mg, 0.46 mg and 0.92 mg.
INDICATIONS: ZEPOSIA® is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.
Zeposia is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.
DOSAGE AND ADMINISTRATION: Treatment should be initiated under the supervision of a physician experienced in the management of multiple sclerosis (MS) or ulcerative colitis (UC). The recommended dose is 0.92 mg ozanimod once daily. An initial dose escalation regimen of ozanimod from Day 1 to Day 7 is required. Days 1-4 dose will be 0.23 mg once daily, Days 5-7 dose will be 0.46 mg once daily, Days 8 and thereafter once daily dose will be 0.92 mg. Refer to the SmPC for dosing recommendations and re-initiation of therapy following treatment interruption.
Special populations: *Adults over 55 years old and elderly population*: No dose adjustment needed and caution should be used in patients over 55 years of age. There are limited data available on RRMS patients > 55 years of age and on UC patients ≥ 65 years of age. No dose adjustment is needed in patients over 55 years of age.
Caution should be used in MS patients over 55 years and in UC patients over 65 years of age, given the limited data available and potential for an increased risk of adverse reactions in this population, especially with long-term treatment. *Renal and hepatic impairment*: No dose adjustment is necessary for patients with renal impairment. Patients with mild or moderate chronic hepatic impairment (Child-Pugh class A or B) are recommended to complete the 7-day dose escalation regimen, and then take 0.92 mg once every other day.
Ozanimod was not evaluated in patients with severe hepatic impairment. Therefore, patients with severe hepatic impairment (Child-Pugh class C) must not be treated with ozanimod. *Paediatric population*: The safety and efficacy in children and adolescents aged below 18 years have not yet been established. See SmPC for further information on Special Populations.
CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Immunodeficient state. Patients who in the last 6 months experienced myocardial infarction (MI), unstable angina, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation or New York Heart Association (NYHA) Class III/IV heart failure. Patients with 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 active infections, active chronic infections such as hepatitis and tuberculosis. Active malignancies. Severe hepatic impairment (Child-Pugh class C). During pregnancy and in women of childbearing potential not using effective contraception.
WARNINGS AND PRECAUTIONS: Bradyarrhythmia: *Initiation of treatment with ozanimod*: Prior to treatment initiation with ozanimod, an ECG in all patients should be obtained to determine whether any pre-existing cardiac abnormalities are present. In patients with certain pre-existing conditions, first-dose monitoring is recommended. Initiation of ozanimod may result in transient reductions in heart rate (HR) and therefore the initial dose escalation regimen to reach the maintenance dose (0.92 mg) on day 8 should be followed. After the initial dose of ozanimod 0.23 mg, the HR decrease started at Hour 4, with the greatest mean reduction at Hour 5, returning towards baseline at Hour 6. With continued dose escalation, there were no clinically relevant HR decreases. Heart rates below 40 beats per minute were not observed. If necessary, the decrease in HR induced by ozanimod can be reversed by parenteral doses of atropine or isoprenaline. Caution should be applied when ozanimod is initiated in patients receiving treatment with a beta-blocker or a calcium-channel blocker (e.g. diltiazem and verapamil). Refer to SmPC for further information. *First dose monitoring in patients with certain pre-existing cardiac conditions:* Due to the risk of transient decreases in HR with the initiation of ozanimod, first-dose, 6-hour monitoring for signs and symptoms of symptomatic bradycardia is recommended in patients with resting HR <55 bpm, second-degree [Mobitz type I] AV block or a history of myocardial infarction or heart failure. Patients should be monitored with hourly pulse and blood pressure measurement during this 6-hour period. An ECG prior to and at the end of this 6-hour period is recommended. Additional monitoring may be required at the end of the 6-hour monitoring period, please refer to SmPC for further information. *Cardiologist advice should be obtained before initiation of ozanimod in the following patients to decide if ozanimod can safely be initiated and to determine the most appropriate monitoring strategy:* History of cardiac arrest, cerebrovascular disease, uncontrolled hypertension, or severe untreated sleep apnoea, history of recurrent syncope or symptomatic bradycardia. Pre-existing significant QT interval prolongation (QTc greater than 500 msec) or other risks for QT prolongation, and patients on medicinal products other than beta-blockers and calcium-channel blockers that may potentiate bradycardia. Patients on class Ia (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol) antiarrhythmic medicinal products, which have been associated with cases of torsades de pointes in patients with bradycardia have not been studied with ozanimod. Liver function: Elevations of aminotransferases may occur in patients receiving ozanimod. Recent (i.e. within last 6 months) transaminase and bilirubin levels should be available before initiation of treatment with ozanimod. In the absence of clinical symptoms, liver transaminases and bilirubin levels should be monitored at Months 1, 3, 6, 9 and 12 on therapy and periodically thereafter. Patients who develop symptoms suggestive of hepatic dysfunction should have hepatic enzymes checked and ozanimod should be discontinued if significant liver injury is confirmed. Patients with pre-existing liver disease may be at increased risk of developing elevated hepatic enzymes when taking ozanimod. Ozanimod has not been studied in patients with severe pre-existing hepatic injury (Child-Pugh class C) and must not be used in these patients. Refer to SmPC. Immunosuppressive effects: Ozanimod has an immunosuppressive effect that predisposes patients to a risk of infection and may increase the risk of developing malignancies, including those of the skin. Physicians should carefully monitor patients, especially those with concurrent conditions or known factors, such as previous immunosuppressive therapy. If this risk is suspected, discontinuation of treatment should be considered by the physician on a case-by-case basis. Infections: Ozanimod causes a mean reduction in peripheral blood lymphocyte count to approximately 45% of baseline values because of reversible retention of lymphocytes in the lymphoid tissues. Ozanimod may increase the susceptibility to infections. Assessments of full blood count are also recommended periodically during treatment. Refer to SmPC. Prior and concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies: In MS and UC clinical studies, patients who received ozanimod were not to receive concomitant antineoplastic, non-corticosteroid immunosuppressive (e.g. azathioprine and 6-mercaptopurine in UC), or immune-

modulating therapies used for treatment of MS and UC. Concomitant use of ozanimod with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies would be expected to increase the risk of immunosuppression and should be avoided. Progressive multifocal leukoencephalopathy (PML): PML has been reported in patients treated with S1P receptor modulators, including ozanimod, and other therapies for (MS and UC). John Cunningham virus (JCV) infection resulting in PML has been associated with some risk factors (e.g., polytherapy with immunosuppressants, severely immunocompromised patients). If PML is suspected, treatment with ozanimod should be suspended until PML has been excluded. If confirmed, treatment with ozanimod should be discontinued. Vaccinations: The use of live attenuated vaccines should be avoided during and for 3 months after treatment with ozanimod. If live attenuated vaccine immunizations are required, these should be administered at least 1 month prior to initiation of ozanimod. Varicella Zoster Virus (VZV) vaccination of patients without documented immunity to VZV is recommended prior to initiating treatment with ozanimod. Cutaneous neoplasms*: Since there is a potential risk of malignant skin growths, patients treated with ozanimod should be cautioned against exposure to sunlight without protection. These patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy. Macular oedema: Macular oedema with or without visual symptoms was observed with ozanimod in patients with pre-existing risk factors or comorbid conditions. Patients with a history of uveitis or diabetes mellitus or underlying/co existing retinal disease are at increased risk of macular oedema. It is recommended that patients with diabetes mellitus, uveitis or a history of retinal disease undergo an ophthalmological evaluation prior to treatment initiation with ozanimod 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 ozanimod should be discontinued. A decision on whether ozanimod should be re-initiated after resolution needs to take into account the potential benefits and risks for the individual patient. Posterior reversible encephalopathy syndrome (PRES)*: If PRES is suspected, treatment with ozanimod should be discontinued. Blood pressure effects. Blood pressure should be regularly monitored during treatment with ozanimod. Respiratory effects: Ozanimod should be used with caution in patients with severe respiratory disease, pulmonary fibrosis and chronic obstructive pulmonary disease. Concomitant medicinal products: The coadministration with, inhibitors of monoamine oxidase (MAO), or CYP2C8 inducer (e.g. rifampicin) with ozanimod is not recommended. Women of childbearing potential: Ozanimod is contraindicated during pregnancy and in women of childbearing potential not using effective contraception. Before initiation of treatment, women of childbearing potential must be informed of this risk to the foetus, must have a negative pregnancy test and must use effective contraception during treatment, and for 3 months after treatment discontinuation. Return of MS disease activity (rebound) after ozanimod discontinuation: Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of another S1P receptor modulator. The possibility of severe exacerbation of disease after stopping ozanimod treatment should be considered. Patients should be observed for relevant signs of possible severe exacerbation or return of high disease activity upon ozanimod discontinuation and appropriate treatment should be instituted as required.

**Serious*

DRUG INTERACTIONS: Effect of inhibitors of the breast cancer resistance protein (BCRP) on ozanimod: Coadministration of ozanimod with ciclosporin, a strong BCRP inhibitor, had no effect on the exposure of ozanimod and its major active metabolites (CC112273 and CC1084037). Effect of inhibitors of CYP2C8 on ozanimod: Caution should be exercised for concomitant use of ozanimod with strong CYP2C8 inhibitors (e.g. gemfibrozil, clopidogrel). Effect of inducers of CYP2C8 on ozanimod: Coadministration of CYP2C8 inducers (i.e. rifampicin) with ozanimod is not recommended. Effect of inhibitors of monoamine oxidase (MAO) on ozanimod: Coadministration of MAO inhibitors (e.g., selegiline, phenelzine) with ozanimod is not recommended. Effects of ozanimod on medicinal products that slow heart rate or atrioventricular conduction (e.g., beta blockers or calcium channel blockers): Caution should be applied when ozanimod is initiated in patients receiving treatment with a beta-blocker or a calcium-channel blocker. Patients on other bradycardic medicinal products and on antiarrhythmic medicinal products (which have been associated with cases of torsades de pointes in patients with bradycardia) have not been studied with ozanimod. Vaccination: During and for up to 3 months after treatment with ozanimod, vaccination may be less effective. The use of live attenuated vaccines may carry a risk of infections and should, therefore, be avoided during and for up to 3 months after treatment with ozanimod.

Anti-neoplastic, immunomodulatory or non-corticosteroid immunosuppressive therapies: Anti-neoplastic, immunomodulatory or non-corticosteroid immunosuppressive therapies should not be co-administered due to the risk of additive immune system effects.

FERTILITY, PREGNANCY AND LACTATION: See 'Special warnings and precautions' section for information on pregnancy. *Breast-feeding:* Breast-feeding should be discontinued during therapy with ozanimod. *Fertility:* No fertility data are available in humans.

UNDESIRABLE EFFECTS: *Very common (≥ 1/10) or Common (≥ 1/100 to < 1/10) Adverse Drug Reactions reported in MS and UC clinical studies:* Alanine aminotransferase increased*, Blood bilirubin increased*, Bradycardia*, Gamma-glutamyl transferase increased*, Headache, Herpes simplex, Herpes zoster, Hypertension*, Lymphopenia, Nasopharyngitis, Orthostatic hypotension, Peripheral oedema, Pharyngitis, Pulmonary function test abnormal*, Respiratory tract infection viral, Urinary tract infection*.

Serious.

Other Serious Adverse Drug Reactions (frequencies based on MS and UC studies): Uncommon (≥1/1,000 to <1/100): Hypersensitivity (including rash and urticaria), Macular oedema; Rare (≥1/10,000 to <1/1,000): progressive multifocal leukoencephalopathy.

Refer to SPC for full details on adverse reactions

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER:

Treatment initiation pack Zeposia 0.23 mg/ 0.46 mg hard capsules - EU/1/20/1442/001 (Pack size of 7; 4 x 0.23 mg and 3 x 0.46 mg) hard capsules; Maintenance pack - Zeposia 0.92 mg hard capsules - EU/1/20/1442/002 (Pack size of 28 hard capsules)

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland

FOR FURTHER INFORMATION CONTACT:

medical.information@bms.com or 1 800 749 749 (Ireland)

Date of preparation: July 2023

Approval code: 2084-IE-2300016

ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Adverse events should be reported. Reporting forms and information can be found via:
HPRA Pharmacovigilance at www.hpra.ie
Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or
1 800 749 749 (Ireland).

ZEPOSIA®▼(ozanimod) PRESCRIBING INFORMATION
United Kingdom

Consult Summary of Product Characteristics (SmPC) before prescribing.
▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

PRESENTATION: Hard capsule containing ozanimod 0.23 mg, 0.46 mg and 0.92 mg.
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Ozanimod was not evaluated in patients with severe hepatic impairment. Therefore, patients with severe hepatic impairment (Child-Pugh class C) must not be treated with ozanimod. *Paediatric population*: The safety and efficacy in children and adolescents aged below 18 years have not yet been established. See SmPC for further information on Special Populations.
CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Immunodeficient state. Patients who in the last 6 months experienced myocardial infarction (MI), unstable angina, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation or New York Heart Association (NYHA) Class III/IV heart failure. Patients with 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 active infections, active chronic infections such as hepatitis and tuberculosis. Active malignancies. Severe hepatic impairment (Child-Pugh class C). During pregnancy and in women of childbearing potential not using effective contraception.
WARNINGS AND PRECAUTIONS: Bradyarrhythmia: *Initiation of treatment with ozanimod*: Prior to treatment initiation with ozanimod, an ECG in all patients should be obtained to determine whether any pre-existing cardiac abnormalities are present. In patients with certain pre-existing conditions, first-dose monitoring is recommended. Initiation of ozanimod may result in transient reductions in heart rate (HR) and therefore the initial dose escalation regimen to reach the maintenance dose (0.92 mg) on day 8 should be followed. After the initial dose of ozanimod 0.23 mg, the HR decrease started at Hour 4, with the greatest mean reduction at Hour 5, returning towards baseline at Hour 6. With continued dose escalation, there were no clinically relevant HR decreases. Heart rates below 40 beats per minute were not observed. If necessary, the decrease in HR induced by ozanimod can be reversed by parenteral doses of atropine or isoprenaline. Caution should be applied when ozanimod is initiated in patients receiving treatment with a beta-blocker or a calcium-channel blocker (e.g. diltiazem and verapamil). Refer to SmPC for further information. *First dose monitoring in patients with certain pre-existing cardiac conditions:* Due to the risk of transient decreases in HR with the initiation of ozanimod, first-dose, 6-hour monitoring for signs and symptoms of symptomatic bradycardia is recommended in patients with resting HR <55 bpm, second-degree [Mobitz type I] AV block or a history of myocardial infarction or heart failure. Patients should be monitored with hourly pulse and blood pressure measurement during this 6-hour period. An ECG prior to and at the end of this 6-hour period is recommended. Additional monitoring may be required at the end of the 6-hour monitoring period, please refer to SmPC for further information. *Cardiologist advice should be obtained before initiation of ozanimod in the following patients to decide if ozanimod can safely be initiated and to determine the most appropriate monitoring strategy:* History of cardiac arrest, cerebrovascular disease, uncontrolled hypertension, or severe untreated sleep apnoea, history of recurrent syncope or symptomatic bradycardia. Pre-existing significant QT interval prolongation (QTc greater than 500 msec) or other risks for QT prolongation, and patients on medicinal products other than beta-blockers and calcium-channel blockers that may potentiate bradycardia. Patients on class Ia (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol) antiarrhythmic medicinal products, which have been associated with cases of torsades de pointes in patients with bradycardia have not been studied with ozanimod. Liver function: Elevations of aminotransferases may occur in patients receiving ozanimod. Recent (i.e. within last 6 months) transaminase and bilirubin levels should be available before initiation of treatment with ozanimod. In the absence of clinical symptoms, liver transaminases and bilirubin levels should be monitored at Months 1, 3, 6, 9 and 12 on therapy and periodically thereafter. Patients who develop symptoms suggestive of hepatic dysfunction should have hepatic enzymes checked and ozanimod should be discontinued if significant liver injury is confirmed. Patients with pre-existing liver disease may be at increased risk of developing elevated hepatic enzymes when taking ozanimod. Ozanimod has not been studied in patients with severe pre-existing hepatic injury (Child-Pugh class C) and must not be used in these patients. Refer to SmPC. Immunosuppressive effects: Ozanimod has an immunosuppressive effect that predisposes patients to a risk of infection and may increase the risk of developing malignancies, including those of the skin. Physicians should carefully monitor patients, especially those with concurrent conditions or known factors, such as previous immunosuppressive therapy. If this risk is suspected, discontinuation of treatment should be considered by the physician on a case-by-case basis. Infections: Ozanimod causes a mean reduction in peripheral blood lymphocyte count to approximately 45% of baseline values because of reversible retention of lymphocytes in the lymphoid tissues. Ozanimod may increase the susceptibility to infections. Assessments of full blood count are also recommended periodically during treatment. Refer to SmPC. Prior and concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies: In MS and UC clinical studies, patients who received ozanimod were not to receive concomitant antineoplastic, non-corticosteroid immunosuppressive (e.g. azathioprine and 6-mercaptopurine in UC), or immune-

modulating therapies used for treatment of MS and UC. Concomitant use of ozanimod with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies would be expected to increase the risk of immunosuppression and should be avoided. Progressive multifocal leukoencephalopathy (PML): PML has been reported in patients treated with S1P receptor modulators, including ozanimod, and other therapies for (MS and UC). John Cunningham virus (JCV) infection resulting in PML has been associated with some risk factors (e.g., polytherapy with immunosuppressants, severely immunocompromised patients). If PML is suspected, treatment with ozanimod should be suspended until PML has been excluded. If confirmed, treatment with ozanimod should be discontinued. Vaccinations: The use of live attenuated vaccines should be avoided during and for 3 months after treatment with ozanimod. If live attenuated vaccine immunizations are required, these should be administered at least 1 month prior to initiation of ozanimod. Varicella Zoster Virus (VZV) vaccination of patients without documented immunity to VZV is recommended prior to initiating treatment with ozanimod. Cutaneous neoplasms*: Since there is a potential risk of malignant skin growths, patients treated with ozanimod should be cautioned against exposure to sunlight without protection. These patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy. Macular oedema: Macular oedema with or without visual symptoms was observed with ozanimod in patients with pre-existing risk factors or comorbid conditions. Patients with a history of uveitis or diabetes mellitus or underlying/co existing retinal disease are at increased risk of macular oedema. It is recommended that patients with diabetes mellitus, uveitis or a history of retinal disease undergo an ophthalmological evaluation prior to treatment initiation with ozanimod 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 ozanimod should be discontinued. A decision on whether ozanimod should be re-initiated after resolution needs to take into account the potential benefits and risks for the individual patient. Posterior reversible encephalopathy syndrome (PRES)*: If PRES is suspected, treatment with ozanimod should be discontinued. Blood pressure effects. Blood pressure should be regularly monitored during treatment with ozanimod. Respiratory effects: Ozanimod should be used with caution in patients with severe respiratory disease, pulmonary fibrosis and chronic obstructive pulmonary disease. Concomitant medicinal products: The coadministration with, inhibitors of monoamine oxidase (MAO), or CYP2C8 inducer (e.g. rifampicin) with ozanimod is not recommended. Women of childbearing potential: Ozanimod is contraindicated during pregnancy and in women of childbearing potential not using effective contraception. Before initiation of treatment, women of childbearing potential must be informed of this risk to the foetus, must have a negative pregnancy test and must use effective contraception during treatment, and for 3 months after treatment discontinuation. Return of MS disease activity (rebound) after ozanimod discontinuation: Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of another S1P receptor modulator. The possibility of severe exacerbation of disease after stopping ozanimod treatment should be considered. Patients should be observed for relevant signs of possible severe exacerbation or return of high disease activity upon ozanimod discontinuation and appropriate treatment should be instituted as required.

*_Serious_

DRUG INTERACTIONS: Effect of inhibitors of the breast cancer resistance protein (BCRP) on ozanimod: Coadministration of ozanimod with ciclosporin, a strong BCRP inhibitor, had no effect on the exposure of ozanimod and its major active metabolites (CC112273 and CC1084037). Effect of inhibitors of CYP2C8 on ozanimod: Caution should be exercised for concomitant use of ozanimod with strong CYP2C8 inhibitors (e.g. gemfibrozil, clopidogrel). Effect of inducers of CYP2C8 on ozanimod: Coadministration of CYP2C8 inducers (i.e. rifampicin) with ozanimod is not recommended. Effect of inhibitors of monoamine oxidase (MAO) on ozanimod: Coadministration of MAO inhibitors (e.g., selegiline, phenelzine) with ozanimod is not recommended. Effects of ozanimod on medicinal products that slow heart rate or atrioventricular conduction (e.g., beta blockers or calcium channel blockers): Caution should be applied when ozanimod is initiated in patients receiving treatment with a beta-blocker or a calcium-channel blocker. Patients on other bradycardic medicinal products and on antiarrhythmic medicinal products (which have been associated with cases of torsades de pointes in patients with bradycardia) have not been studied with ozanimod. Vaccination: During and for up to 3 months after treatment with ozanimod, vaccination may be less effective. The use of live attenuated vaccines may carry a risk of infections and should, therefore, be avoided during and for up to 3 months after treatment with ozanimod.

Anti-neoplastic, immunomodulatory or non-corticosteroid immunosuppressive therapies: Anti-neoplastic, immunomodulatory or non-corticosteroid immunosuppressive therapies should not be co-administered due to the risk of additive immune system effects.

FERTILITY, PREGNANCY AND LACTATION: See 'Special warnings and precautions' section for information on pregnancy. *Breast-feeding:* Breast-feeding should be discontinued during therapy with ozanimod. *Fertility:* No fertility data are available in humans.

UNDESIRABLE EFFECTS: *Very common (≥ 1/10) or Common (≥ 1/100 to < 1/10) Adverse Drug Reactions reported in MS and UC clinical studies:* Alanine aminotransferase increased*, Blood bilirubin increased*, Bradycardia*, Gamma-glutamyl transferase increased*, Headache, Herpes simplex, Herpes zoster, Hypertension*, Lymphopenia, Nasopharyngitis, Orthostatic hypotension, Peripheral oedema, Pharyngitis, Pulmonary function test abnormal*, Respiratory tract infection viral, Urinary tract infection*.

*_Serious_.

Other Serious Adverse Drug Reactions (frequencies based on MS and UC studies): Uncommon (≥1/1,000 to <1/100): Hypersensitivity (including rash and urticaria), Macular oedema; Rare (≥1/10,000 to <1/1,000): progressive multifocal leukoencephalopathy.

Refer to SPC for full details on adverse reactions

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER and BASIC NHS PRICE:
Great Britain: PLGB 15105/0114 and PLGB 15105/0115 / Northern Ireland: EU/1/20/1442/001 and EU/1/20/1442/002.
Treatment initiation pack Zeposia 0.23 mg/ 0.46 mg hard capsules (Pack size of 7; 4 x 0.23 mg and 3 x 0.46 mg) hard capsules - £343.25, Maintenance pack - Zeposia 0.92 mg hard capsules (Pack size of 28 hard capsules) - £1,373.00

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland

FOR FURTHER INFORMATION CONTACT:
medical.information@bms.com or 0800 731 1736 (United Kingdom).

Date of preparation: July 2023

Approval code: 2084-GB-2300330

ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Adverse events should be reported. Reporting forms and information can be found via:
The yellow card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA
Yellow Card in the Google Play or Apple App Store;
Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or
0800 731 1736 (United Kingdom)