Velsipity® (etrasimod)▼

Prescriber Checklist

This educational material is part of the marketing authorisation and has been approved by the HPRA.

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Pfizer

December 2024 PP-V1A-IRI-0004

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance: www.hpra.ie. When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates. Any suspected adverse reactions with etrasimod may also be reported to Pfizer Medical Information on 1800 633 363.

To order additional copies of these educational materials, please contact Pfizer Medical Information on 1800 633 363. Electronic copies of the etrasimod educational materials are available at www.hpra.ie (enter 'Velsipity' in the 'Find a medicine' search box and click 'EdM' under the 'Documents' column).

For full details please refer to the Summary of Product Characteristics (SmPC) which may also be obtained by electronic download from https://www.medicines.ie.

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Patient: _____

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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

An electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities	☐
Etrasimod must not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. • with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Obtain cardiologist advice before initiation of etrasimod to determine overall benefit risk and the most appropriate monitoring strategy in patients with the following conditions: - Significant QT prolongation (QTcF ≥ 450 msec in males, ≥ 470 msec in females). - Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic medicinal products. - Unstable ischaemic heart disease, history of cardiac arrest, cerebrovascular disease (occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension. - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnoea.	☐
Caution should be taken when initiating etrasimod in patients taking medicines known to decrease heart rate.	☐
Etrasimod should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
Check patient's recent (i.e. within the last 6 months) liver function test results for transaminase and bilirubin levels • Etrasimod must not be used in patients with severe hepatic impairment.	☐
In women of childbearing potential, a pregnancy test must be negative. • Confirm a negative pregnancy test result prior to starting treatment. • Women of childbearing potential must be counselled on risk for the foetus. • Provide a Pregnancy-Specific Patient Card to all female patients of childbearing potential. • Etrasimod must not be used during pregnancy or in women of childbearing potential not using effective contraception.	☐
An ophthalmic evaluation is recommended in patients with a history of diabetes mellitus, uveitis, and/or underlying/co-existing retinal disease, who are at increased risk of developing macular oedema. • Patients with macular oedema should not use etrasimod.	☐
Provide all patients/caregivers with a patient/caregiver guide.	☐

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PP-V1A-IRI-0004 December 2024

Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
If a patient develops a serious infection, interruption of etrasimod should be considered	☐
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐
Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	☐
The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (PRES). • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with etrasimod should be discontinued if PRES is suspected.	☐

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The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (PRES). • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with etrasimod should be discontinued if PRES is suspected.	☐

Velsipity® ▼ (etrasimod)

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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

An electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities	☐
Etrasimod must not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. • with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Obtain cardiologist advice before initiation of etrasimod to determine overall benefit risk and the most appropriate monitoring strategy in patients with the following conditions: - Significant QT prolongation (QTcF ≥ 450 msec in males, ≥ 470 msec in females). - Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic medicinal products. - Unstable ischaemic heart disease, history of cardiac arrest, cerebrovascular disease (occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension. - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnoea.	☐
Caution should be taken when initiating etrasimod in patients taking medicines known to decrease heart rate.	☐
Etrasimod should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
Check patient's recent (i.e. within the last 6 months) liver function test results for transaminase and bilirubin levels • Etrasimod must not be used in patients with severe hepatic impairment.	☐
In women of childbearing potential, a pregnancy test must be negative. • Confirm a negative pregnancy test result prior to starting treatment. • Women of childbearing potential must be counselled on risk for the foetus. • Provide a Pregnancy-Specific Patient Card to all female patients of childbearing potential. • Etrasimod must not be used during pregnancy or in women of childbearing potential not using effective contraception.	☐
An ophthalmic evaluation is recommended in patients with a history of diabetes mellitus, uveitis, and/or underlying/co-existing retinal disease, who are at increased risk of developing macular oedema. • Patients with macular oedema should not use etrasimod.	☐
Provide all patients/caregivers with a patient/caregiver guide.	☐

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
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Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
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Prior to treatment with etrasimod

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
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• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
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Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
If a patient develops a serious infection, interruption of etrasimod should be considered	☐
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐
Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	☐
The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (PRES). • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with etrasimod should be discontinued if PRES is suspected.	☐

Velsipity® ▼ (etrasimod)

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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

An electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities	☐
Etrasimod must not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. • with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Obtain cardiologist advice before initiation of etrasimod to determine overall benefit risk and the most appropriate monitoring strategy in patients with the following conditions: - Significant QT prolongation (QTcF ≥ 450 msec in males, ≥ 470 msec in females). - Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic medicinal products. - Unstable ischaemic heart disease, history of cardiac arrest, cerebrovascular disease (occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension. - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnoea.	☐
Caution should be taken when initiating etrasimod in patients taking medicines known to decrease heart rate.	☐
Etrasimod should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
Check patient's recent (i.e. within the last 6 months) liver function test results for transaminase and bilirubin levels • Etrasimod must not be used in patients with severe hepatic impairment.	☐
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An ophthalmic evaluation is recommended in patients with a history of diabetes mellitus, uveitis, and/or underlying/co-existing retinal disease, who are at increased risk of developing macular oedema. • Patients with macular oedema should not use etrasimod.	☐
Provide all patients/caregivers with a patient/caregiver guide.	☐

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
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The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
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Monitoring activities during and after treatment

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Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
If a patient develops a serious infection, interruption of etrasimod should be considered	☐
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐
Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	☐
The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

An electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities	☐
Etrasimod must not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. • with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Obtain cardiologist advice before initiation of etrasimod to determine overall benefit risk and the most appropriate monitoring strategy in patients with the following conditions: - Significant QT prolongation (QTcF ≥ 450 msec in males, ≥ 470 msec in females). - Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic medicinal products. - Unstable ischaemic heart disease, history of cardiac arrest, cerebrovascular disease (occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension. - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnoea.	☐
Caution should be taken when initiating etrasimod in patients taking medicines known to decrease heart rate.	☐
Etrasimod should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
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An ophthalmic evaluation is recommended in patients with a history of diabetes mellitus, uveitis, and/or underlying/co-existing retinal disease, who are at increased risk of developing macular oedema. • Patients with macular oedema should not use etrasimod.	☐
Provide all patients/caregivers with a patient/caregiver guide.	☐

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
If a patient develops a serious infection, interruption of etrasimod should be considered	☐
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐
Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	☐
The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (PRES). • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with etrasimod should be discontinued if PRES is suspected.	☐

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Prior to treatment with etrasimod

Lists of tests and checks to be conducted prior to treatment initiation with etrasimod

An electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities	☐
Etrasimod must not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. • with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Obtain cardiologist advice before initiation of etrasimod to determine overall benefit risk and the most appropriate monitoring strategy in patients with the following conditions: - Significant QT prolongation (QTcF ≥ 450 msec in males, ≥ 470 msec in females). - Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic medicinal products. - Unstable ischaemic heart disease, history of cardiac arrest, cerebrovascular disease (occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension. - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnoea.	☐
Caution should be taken when initiating etrasimod in patients taking medicines known to decrease heart rate.	☐
Etrasimod should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
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Monitoring activities during and after treatment

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A recent complete blood count (CBC) (i.e. within the last 6 months or after discontinuation of prior ulcerative colitis therapy), including lymphocyte count, should be obtained. • Etrasimod should not be used in patients with an absolute lymphocyte count < 0.2 x 10^9/L.	☐
Check patient's recent (i.e. within the last 6 months) liver function test results for transaminase and bilirubin levels • Etrasimod must not be used in patients with severe hepatic impairment.	☐
In women of childbearing potential, a pregnancy test must be negative. • Confirm a negative pregnancy test result prior to starting treatment. • Women of childbearing potential must be counselled on risk for the foetus. • Provide a Pregnancy-Specific Patient Card to all female patients of childbearing potential. • Etrasimod must not be used during pregnancy or in women of childbearing potential not using effective contraception.	☐
An ophthalmic evaluation is recommended in patients with a history of diabetes mellitus, uveitis, and/or underlying/co-existing retinal disease, who are at increased risk of developing macular oedema. • Patients with macular oedema should not use etrasimod.	☐
Provide all patients/caregivers with a patient/caregiver guide.	☐

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Refer to section 4.8 of the SmPC for how to report adverse reactions.

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Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose:	
• 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	☐
Additional monitoring is recommended in patients, if at the end of 4-hour period:	
• Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	☐
Blood pressure should be monitored during treatment with etrasimod and managed appropriately	☐
When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Assessments of CBC are recommended periodically during treatment • Absolute lymphocyte counts < 0.2 x 10^9/L, if confirmed, should lead to interruption of etrasimod therapy until the level reaches > 0.5 x 10^9/L when re-initiation of etrasimod can be considered.	☐
If a patient develops a serious infection, interruption of etrasimod should be considered	☐
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐
Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	☐
The use of live attenuated vaccines should be avoided for at least 2 weeks after discontinuation of treatment with etrasimod.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Etrasimod should be discontinued if significant liver injury is confirmed.	☐
To avoid pregnancy, women of childbearing potential must use effective contraception during treatment and for at least 14 days after stopping etrasimod. • Pregnancy testing should be repeated regularly. • If a woman becomes pregnant during treatment, etrasimod must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/coexisting retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
In patients without risk factors for macular oedema (such as history of diabetes mellitus, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting etrasimod treatment (cases reported with etrasimod occurred within this timeframe) and at any time if there is a change in vision while taking etrasimod.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.	☐
Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (PRES). • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with etrasimod should be discontinued if PRES is suspected.	☐

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