North Central London
Joint Formulary Committee

Transfer of Prescribing Document

Lacosamide [Vimpat®]

Treatment of Focal Seizures (partial-onset) with or without secondary generalisation in patients aged 16 years and older

Document Control		
Date	**Version**	**Action**
February 2020	V1.0	Factsheet produced by National Hospital for Neurology and Neurosurgery (NHNN)
July 2024	V2.0	Adapted to new North Central London (NCL) template for Transfer of Prescribing Documents. References reviewed and updated.

Background Information

Transfer of prescribing documents support primary care prescribers in taking ongoing responsibility for continuing a medicine initiated in secondary care. It differs from a shared care agreement where secondary care retain a proportion of responsibility for ongoing care.

This document has been discussed by the NCL Shared Care Group with a decision that a full Shared Care Guideline is not required. However, this document has undergone the same due processes and extensive consultation across the region from specialists, primary care prescribers and Integrated Care Board (ICB) teams, specifically acknowledging that primary care providers outside of NCL will need to utilise it. Please find a link to the document development process outlined *here*. Further information on shared care, including out of area referrals, can be found in the NCL Interface Prescribing Guidance.

Indication information

Lacosamide is licensed as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. Treatment should be initiated by a specialist with expertise in the treatment of epilepsy who will consider contraindications and cautions (British National Formulary BNF & Summary of Product Characteristics SmPC) for use.

Prior to transfer of care, the hospital team will:

1. Provide the patient with information regarding the treatment and possible adverse effects: In particular, advise patients of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting) & advise to seek immediate medical advice if these symptoms occur.
2. Decide with the patient how they will document their seizure type and frequency. This may be by providing a seizure diary to the patient or agreeing for the patient to document this information in their own diary or electronic device.
3. Perform a baseline electrocardiogram (ECG) in all patients and follow up ECG in high-risk patients.
4. Initiate and optimise (stabilise) treatment and inform the GP when the patient is stable on dose so that the GP can continue prescribing, including whether lacosamide is used as monotherapy or adjuvant therapy (timescale will be dependent on individual dose titration but typically after 3 months).
5. Ongoing monitoring: 3 months after initiation followed by 6-monthly follow-up appointments. Dosing adjustments are to be done by the hospital and this information communicated to the GP in writing within 14 days.

Dose

Initial stabilisation (by specialist team):

Dosing recommendations in adolescents and children ≥50kg and adults:

	Monotherapy	**Adjunctive therapy**
Starting dose	50mg to 100mg twice daily	50mg twice daily
Single loading dose (if applicable)	200 mg	200 mg
Titration (incremental steps)	50 mg twice a day (100 mg/day) at weekly intervals	50 mg twice a day (100 mg/day) at weekly intervals
Maximum recommended dose	Up to 300mg twice daily (i.e. up to 600 mg/day)	Up to 200mg twice daily (i.e. up to 400 mg/day)

Dosing recommendations in adolescents weighing less than 50 kg		
Starting dose	**Titration (incremental steps)**	**Maximum recommended dose**
Monotherapy and Adjunctive therapy: 1 mg/kg twice a day (2 mg/kg/day)	1 mg/kg twice a day (2 mg/kg/day) at weekly intervals	**Monotherapy:** - up to 6 mg/kg twice a day (12 mg/kg/day) in patients ≥ 10 kg to < 40 kg - up to 5 mg/kg twice a day (10 mg/kg/day) in patients ≥ 40 kg to < 50 kg
		Adjunctive therapy: - up to 6 mg/kg twice a day (12 mg/kg/day) in patients ≥ 10 kg to < 20 kg - up to 5 mg/kg twice a day (10 mg/kg/day) in patients ≥ 20 kg to < 30 kg - up to 4 mg/kg twice a day (8 mg/kg/day) in patients ≥ 30 kg to < 50 kg

The maximum licensed dose is 600mg daily as monotherapy or 400mg daily as adjunctive therapy.

Missed Dose

Lacosamide must be taken twice a day, approximately 12 hours apart.
If a dose is missed, the patient should be instructed to take the missed dose immediately, and then to take the next dose of lacosamide at the regularly scheduled time. If the patient notices the missed dose within 6 hours of the next one, he/she should be instructed to wait to take the next dose of lacosamide at the regularly scheduled time. Patients should not take a double dose.

Maintenance dose:

This is based on individual patient requirements.

Conditions requiring dose adjustment

Further information about prescribing in elderly, pregnant women and patients with hepatic or renal impairment can be found here (link: BNF & SmPC).

Precautions for use

Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products.

High-risk patients will have a follow up ECG after 3 months. Further ECG monitoring will be conducted before a lacosamide dose increase above 400 mg/day and after lacosamide is titrated to steady-state.

	Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur.		
Duration of treatment	Continued unless no longer controlling symptoms		
Stopping criteria and treatment discontinuation	In patients who develop serious cardiac arrhythmia, clinical benefit/risk assessment should be performed and if needed lacosamide should be discontinued. If lacosamide no longer controls symptoms/seizure severity and frequency, patients should be reviewed by the specialist team for alternative treatment If lacosamide has to be discontinued, it is recommended to taper the dose gradually (reducing the daily dose by 200mg/week).		
Monitoring (by specialist)	**<u>Baseline monitoring:</u>** • Baseline seizure type and frequency • Baseline ECG in all patients and follow up ECG in high-risk patients. **<u>Ongoing monitoring:</u>** 3 months after initiation followed by 6-monthly follow-up appointments (unless more frequent monitoring is required based on individual patient needs) • Response to treatment (through seizure diary) • Adverse effects of lacosamide including suicidal ideation and behaviour, cardiac rhythm and conduction abnormalities **<u>ECG monitoring:</u>** Dose-related prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products (see SmPC section 4.5), as well as in elderly patients. **Frequency of test:** In these patients it should be considered to perform an ECG before a lacosamide dose increase above 400 mg/day and after lacosamide is titrated to steady state. Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur.		
Ongoing monitoring (by primary care clinician)	**Test**	**Frequency of test**	**Action if out of range**

If no monitoring is needed, please state this.	Increased frequency/duration of seizures as reported by the patient Symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting)	As reported by the patient	Contact specialist for advice
Adverse effects and management For a full list of adverse effects, please refer to the (link: BNF & SmPC) Healthcare professionals are asked to report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme.	**Adverse effect** *(include those that require specific action and thresholds for test results where applicable)*	**Frequency of ADR (as per SmPC)**	**Action for GP**
	Angioedema	Uncommon	Patient should be advised to seek immediate medical attention (through A&E)
	Increased somnolence	Common	Contact specialist for advice on dose reduction or discontinuation based on severity
	Lacosamide-induced rash (usually on initiation)	Common	Repeat blood test (FBC,CPR,LFT) and contact specialist for advice on dosing or topical treatment of rash.
	Suicidal ideation	Uncommon	Contact specialist to discuss options.
	Dizziness, nausea, headache, diplopia	Very common	Contact specialist to discuss options
Interactions	Lacosamide does not interact with other antiepileptic drugs, warfarin, digoxin, oral contraception. Lacosamide should be used with caution in patients treated with medicinal products known to be associated with PR prolongation (including sodium channel blocking antiepileptic medicinal products) and in patients treated with antiarrhythmics. However, subgroup analysis in clinical studies did not identify an increased magnitude of PR prolongation in patients with concomitant administration of carbamazepine or lamotrigine.		
Advice to patients and carers	The patient should be advised to report any of the above signs or symptoms to their GP/specialist without delay. **GP to note:** Report any patient reported signs of arrhythmias or any new diagnosis of AF, bradycardia and AV block to the specialist for patient review. This is because lacosamide may cause PR interval prolongation		

Resources and key references	1) Summary of Product Characteristics for Vimpat® UCB Pharma Limited last updated on eMC on the 23-Jun-2022 accessed via https://www.medicines.org.uk/emc/product/2278/ on 07/07/2024 2) Summary of Product Characteristics for Vimpat® oral syrup, UCB Pharma Limited last updated on eMC on the 07-Mar-2024 accessed via https://www.medicines.org.uk/emc/product/2285/ on 07/07/2024 3) British National Formulary. Last accessed via https://bnf.nice.org.uk/drugs/lacosamide/ on 07-Jul-2024

Contact Details

National Hospital for Neurology and Neurosurgery (NHNN)	
NHNN Hospital Switchboard	020 3456 7890
NHNN Pharmacy Office	020 3448 3327
Epilepsy Nurse Specialists (please be aware this is an answer phone, but messages are listened to daily)	020 3448 8627
For individual consultants at NHNN, please see letterhead in clinic letters or call via Switchboard	