City and Hackney Clinical Commissioning Group
Homerton University Hospital Foundation Trust

SHARED CARE GUIDELINE

LACOSAMIDE

Treatment of epilepsy in adults and adolescents ≥16 years

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AND FILED IN NOTES

INTRODUCTION – Indication and Licensing

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. The primary mechanism of action of lacosamide is by slow sodium channel blockade.

PATIENT PATHWAY

Clinical Speciality / Indication	**Prescribing Initiated by**	**Prescribing Continued by** ***(detail when suitable for transfer to occur)***	**Monitored by** ***(detail when suitable for transfer to occur IF APPROPRIATE)***	**Duration of treatment**
Neurology/ Epilepsy	Epilepsy Specialist	GP to take over after 2 months or after the patient has been titrated to a stable therapeutic dose.	Effect on seizure control monitored by hospital and GP.	Indefinite if treatment tolerated and effective.

Reviews & dosing adjustments

- The patient will be followed up by the epilepsy specialist team at the hospital for review of treatment efficacy and tolerability. The patient will be given contact details for the team.
- Dosing adjustments are to be done by the hospital and this information communicated to the GP in writing within 14 days.
- Correspondences from GP should be addressed to the 'Consultant Epileptologist' and NOT to neurology.

ORAL DOSE AND ADMINISTRATION

	Initial*	**Titration***	**Maximum dose***
Standard dosing	50mg once daily	Increase weekly by 50mg daily (according to response and tolerability. *Initial maintenance dose:* 100mg twice daily. Increase by 100mg every 2 weeks thereafter to a dose of 200mg bd.	*Adjunctive therapy* 100mg or 200mg twice daily *Monotherapy* 200mg twice daily
Alternative loading regimen	*Administered under medical supervision* 200mg stat followed 12 hours later by 100mg twice daily	Thereafter increase weekly by 50mg twice daily (100mg/day) according to response and tolerability.	*Adjunctive therapy* 100mg or 200mg twice daily *Monotherapy* 100mg or 200mg twice daily
Mild or moderate hepatic impairment	A **maximum dose of 300mg/day** is recommended. Dose titration in these patients should be performed with caution considering co-existing renal impairment. **See the summary of product characteristics for more information.**		
Renal impairment	*CrCl >30ml/min* – no dosing adjustment required, titrate with caution in doses >200mg/day. *CrCl ≤30ml/min* – titrate with caution, **maximum maintenance dose of 250mg/day**. *Haemodialysis* – a supplement of up to 50% of the divided daily dose directly after the end of haemodialysis is recommended. **See the summary of product characteristics for more information.**		
Patients ≥65 years	No dosing adjustment required.		

*Note doses reflect recommendations from the specialist epilepsy clinic and may not be the same as the BNF or SPC.

Other considerations:

- May be taken with or without food.
- Lacosamide (Vimpat®) tablets and oral syrup are bioequivalent.
- **Potential childbearing age –** discuss with the epilepsy specialist team regarding the benefits of treatment, risks in pregnancy and contraceptive advice. All women with epilepsy should be advised to take 5mg daily of folic acid prior to conception and to continue taking this until at least the end of the first trimester to reduce the incidence of major congenital malformation.
- **Driving** – advise the patient to inform the Driver and Vehicle Licensing Agency (DVLA) about their epilepsy. See the Epilepsy Action website for more information.

CAUTIONS

- **Suicidal ideation and behaviour** have been reported in patients treated with anti-epileptic medicinal products in several indications. The available data do not exclude the possibility of an increased risk for lacosamide.
- **Dose-related prolongations in PR interval and second degree or higher AV block -** caution in patients with known conduction problems, severe cardiac disease (e.g. history of myocardial infarction or heart failure), in elderly patients, or when lacosamide is used in combination with products known to be associated with PR prolongation. Consider performing an ECG in these patients before a lacosamide dose increase above 400mg/day and after lacosamide is titrated to steady-state.

CONTRAINDICATIONS

- Known second- or third-degree atrioventricular (AV) block.

INTERACTIONS

- Lacosamide has no specific interaction information.
- **Anticonvulsant effect of antiepileptics reduced by**: selective serotonin reuptake inhibitors, tricyclic (and related) antidepressants, monoamine oxidase inhibitors, antipsychotics, mefloquine and orlistat.

MONITORING STANDARDS FOR MEDICATION AT THE ACUTE NHS TRUST

Seizure diary

- The patient will be given a seizure recording diary, which they will be encouraged to use for the first 6 months of therapy. The patient will be able to record in the diary the nature of the seizure and frequency, and any side effects or problems that they experienced with the treatment.
- A pdf copy of the seizure diary and the Epilepsy Toolkit smartphone app can be downloaded from the Epilepsy Society website (see page 5).

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KEY ADVERSE EFFECTS & ACTIONS

Adverse effects	**Symptoms/signs** *(specify what would prompt action)*	**Actions (***what action should the GP take if identified in primary care)*
Prolongations in PR interval, second or higher degree AV block	**Advise patient to seek medical attention if experiencing:** slow or irregular pulse, feeling of lightheaded and fainting, palpitations, rapid or irregular pulse, shortness of breath.	**Stop medication and seek urgent advice** from the specialist team.
Multi-organ hypersensitivity reactions (DRESS)	Typically present with fever and rash and can be associated with involvement of different organ systems.	**Stop medication and seek urgent advice** from the specialist team.
Dizziness and headache (very common ≥10%)	Incidence may be higher after a loading dose, incidence and severity may decrease over time.	Advise patient not to drive a vehicle, operate complex machinery or engage in other potentially hazardous activities. **Reduce dose if severe** after discussion with the specialist team.
Eye disorders	Double vision (very common ≥10%) and blurred vision.	**Reduce dose if severe** after discussion with the specialist team.
Abnormal liver function tests	AST/ALT >2 times upper limit of normal	Check for concomitant drugs that are known to raise liver enzymes. **Seek advice** from the specialist team.
Gastrointestinal disturbances	Nausea (very common ≥10%), also vomiting, constipation, flatulence, dyspepsia, dry mouth and diarrhoea. Incidence may be higher after a loading dose, incidence and severity may decrease over time.	**Reduce dose if severe** after discussion with the specialist team.

Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

The SCG lists only the key information. Please refer to the current British National Formulary and Summary of Product Characteristics for comprehensive information on cautions, contraindications, interactions and adverse effects.

PREGNANCY AND BREAST FEEDING

- **Pregnancy** – the potential **risk for humans is unknown**. Studies in animals did not indicate any teratogenic effects, but embryotoxicity was observed at maternal toxic doses. All pregnant women with epilepsy, whether taking medication or not, should be encouraged to **notify the UK Epilepsy and Pregnancy Register** (Tel: 0800 389 1248).
- **Breastfeeding** – **AVOID.** It is not known whether lacosamide is excreted in human milk. Animal studies have shown excretion of lacosamide in breast milk.
- **Fertility** – the effect of lacosamide on human fertility has not been established. No adverse reactions on male or female fertility or reproduction were observed in rats at doses producing plasma exposures (AUC) up to approximately 2 times the plasma AUC in humans at the maximum recommended human dose.

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics.

SHARED CARE

Shared care guideline*:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a

system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

Consultant

1. Ensure that the patient/carer is an informed recipient in therapy.
2. Ensure that the patient/carer understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
3. Ensure baseline investigations are normal before commencing treatment.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first 2 months of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical supervision of the patient by routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, and if applicable, most recent blood results and frequency of monitoring are stated.
8. Evaluation of any reported adverse effects by GP or patient.
9. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
10. Inform GP of patients who do not attend clinic appointments.
11. Discuss benefits of treatment, risks in pregnancy and breastfeeding with the patient. Counsel the patient on contraception (if appropriate) and what to do if pregnancy occurs. Document in the notes.
12. Ensure that backup advice is available at all times.

General Practitioner

1. Ensure that the patient/carer understands the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Monitor patient's overall health and well-being.
3. Report any adverse events to the consultant, where appropriate.
4. Report any adverse events to the MHRA / CHM, where appropriate.
5. Help in monitoring the progression of disease.
6. Prescribe the drug treatment as described.
7. Provide contraception advice and prescription as appropriate. Prescribe folic acid if appropriate.

City and Hackney Medicines Management Team

1. To provide feedback to acute trusts via Joint Prescribing and Medicines Management Group.
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support acute trusts in resolving issues that may arise as a result of shared care.

Patient/ Carer

1. Report any adverse effects to their GP and/or specialist
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.
5. Take/ administer the medication as prescribed.
6. Undertake any monitoring as requested by the GP and/or specialist.

Costs

Drug Product	**Cost in primary care**
Vimpat® film coated Lacosamide tablets	**50 mg** (pink), 14-tab pack = £10.81; **100 mg** (yellow), 14-tab pack = £21.62, 56-tab pack = £86.50; **150 mg** (pink), 14-tab pack = £32.44, 56-tab pack £129.74; **200 mg** (blue), 56-tab pack = £144.16
Vimpat® sugar free Lacosamide syrup	10 mg/1 mL, net price 200-mL pack =£25.74

Based on BNF edition 73 (March 2017).

RESOURCES AVAILABLE

- Epilepsy Society accessible via https://www.epilepsysociety.org.uk
- Epilepsy Action accessible via https://www.epilepsy.org.uk

Relevant contact details	
Consultant or Registrar on-call via switchboard	020 8510 5555
Clinical Nurse Specialist	020 8510 5912
Homerton University Hospital NHS Foundation Medicines Information	020 8510 7000
City and Hackney Medicines Management Team	0203 816 3224

References

- SCG template adapted from NELMMN and Barts Health NHS Trust
- Joint Formulary Committee British National Formulary edition 73. Available at https://ebnf.homerton.nhs.uk [accessed 01/06/2017].
- Summary of product characteristics – Vimpat® 50mg film-coated tablets. Available at www.medicines.org.uk [accessed 05/06/2017].
- Royal College of Obstetricians & Gynaecologists. Epilepsy in pregnancy, green-top guideline 68. Available at https://www.rcog.org.uk/globalassets/documents/guidelines/green-top-guidelines/gtg68_epilepsy.pdf [accessed 21/06/2017].

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