BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Lacosamide
Amber ***three months***	
Indication	Monotherapy and adjunctive therapy of focal seizures with or without secondary generalisation in adults with epilepsy.

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	For both monotherapy and adjunctive therapy, the recommended starting dose is 50mg twice daily, increased to 100mg twice daily after one week (Licensed indication). Depending on response and tolerability, the maintenance dose can be further increased at weekly intervals by 50mg twice a day up to a maximum recommended daily dose of 300mg twice daily (monotherapy) or 200mg twice daily (adjunctive therapy). If lacosamide has to be discontinued, it is recommended this be done gradually (e.g. taper the daily dose by 200mg/week). The advice of a specialist experienced in the use of lacosamide should be sought before discontinuation. Lacosamide can be taken with or without food.
Route and formulation	Film-coated tablets and syrup for oral administration. Tablets available in 50mg, 100mg, 150mg and 200mg strengths. Syrup available in 10mg per ml strength. The tablets and syrup are bioequivalent. Brand name is Vimpat. Generics are not currently available.
Duration of treatment	Indefinite, until the specialist advises otherwise.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
Baseline ECG (where required in at-risk patients) will be undertaken in secondary care.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
ECG	As required in at-risk patients (known conduction problems, severe cardiac disease, elderly patients, lacosamide used in combination with products associated with PR prolongation	Specialist team	Lacosamide may need to be discontinued if disturbances in cardiac rhythm and/or conduction occur.

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Suicidal ideation/behaviour	Uncommon	Seek specialist advice.
Dizziness	Very common	Advise patient to avoid driving/ operating machinery. Incidence and severity may decrease over time. Refer back to specialist team if unmanageable.
Headache	Very common	Incidence and severity may decrease over time. Refer back to specialist team if unmanageable.
Double/blurred vision	Common	Advise patient to avoid driving/ operating machinery. Discuss with specialist team.
Insomnia	Common	Refer back to specialist team if unmanageable.
Nausea	Very common	Refer back to specialist team if unmanageable.
Multi-organ hypersensitivity reaction (DRESS) *(Often presents as fever and rash)*	Unknown	Discontinue medication and seek urgent advice from specialist team.
Second degree or higher AV block	Uncommon	Patients should be aware of symptoms of second degree AV block (slow/irregular pulse, light headedness, fainting) and AF or flutter (palpitations, rapid or irregular pulse, shortness of breath). Seek urgent advice from special team if occurs.

Referral back to specialist

- Any patient experiencing unmanageable side effects
- Any patient that is pregnant or considering pregnancy.
- Any patient showing signs of suicidal ideation
- Please refer back to secondary care if advice is needed for unmanaged seizures.
- Where patients require discontinuation of therapy due to side effects or other reasons please refer back to secondary care.

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Drug interactions

- **Drugs associated with PR prolongation and class I antiarrhythmics** - Use with caution alongside medicines associated with PR prolongation (e.g.

	carbamazepine, lamotrigine, eslicarbazepine, pregabalin) and in patients treated with class I antiarrhythmic drugs. - **Strong enzyme inducers** (e.g. rifampicin or St John's Wort) may moderately reduce the systemic exposure of lacosamide. Starting/ending treatment with enzyme inducers should be done with caution. - **Inhibitors of CYP2C9/CYP3A4** - Concomitant treatment with strong inhibitors of CYP2C9 (e.g. fluconazole) and CYP3A4 (e.g. itraconazole, ketoconazole, ritonavir, clarithromycin) may lead to increased plasma concentrations of lacosamide. - Anticonvulsant effect of antiepileptics reduced by SSRIs, tricyclics, monoamine oxidase inhibitors, antipsychotics, orlistat, mefloquine. **Contraindications** - Hypersensitivity to the active substance or excipients (see SPC) - Known second or third degree atrioventricular block **Cautions** - Increased risk of suicidal thoughts and behaviour. Encourage patient to report these if they occur. **Pregnancy/Breastfeeding** - The potential risk of using lacosamide in pregnancy is unknown - Low levels in milk but avoid in breastfeeding due to inadequate information. - Any woman who falls pregnant or wishes to conceive should be referred back to the specialist team. **Renal impairment** - **Mild/moderate impairment** (CrCl > 30ml/min) – no dose adjustment necessary - **Severe impairment** (CrCl ≤30 ml/min) and end stage renal disease – max recommended dose 250mg/day **Hepatic impairment** - **Mild/moderate impairment** – max recommended dose 300mg/day - **Severe impairment** – not studied, use with caution.
Reminder to ask patient about specific problems	Signs of suicidal ideation/behaviour

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Please discuss with specialist team if you wish to conceive or become pregnant
2. Patients should be encouraged to seek medical advice should any signs of suicidal ideation or behaviour emerge.
3. Do not discontinue Lacosamide without discussion with your specialist.
4. Patients should be advised not to drive or operate machinery if they experience dizziness or blurred vision which may affect their ability to perform such activities.

Section 7: Generic principles of shared care for SECONDARY CARE

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood

test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Consultant Neurologist managing patient	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Neurology Registrar on call	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Neurosciences specialist pharmacist(s)	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Amelia Gregory (Epilepsy Specialist Nurse)	North Bristol NHS Trust	Via switchboard (0117 9505050)	Amelia.Gregory@nbt.nhs.uk
Helen Hodgson (Epilepsy Specialist Nurse)	North Bristol NHS Trust	Via switchboard (0117 9505050)	Helen.Hodgson@nbt.nhs.uk

Section 11: Document Details

Date prepared	September 2010 Updated May 2019
Prepared by	Claire Daniels Updated by Gemma Bray (Neurosciences Specialist Pharmacist)
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Section 12: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Draft has been circulated to relevant parties within the local area

Section 13: References

Please list references

1. Summary of Product Characteristics for Vimpat film-coated tablets. Accessed via www.medicines.org.uk. Date accessed: 01-April-2019
2. British National Formulary [online]. Accessed via www.medicinescomplete.com. Date accessed 01-April-2019