

Effective Shared Care Agreement (ESCA)

Lacosamide

ESCA: For the treatment of Lacosamide as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing lacosamide as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel competent to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with epilepsy are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of epilepsy
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
4. Do baseline monitoring prior to initiation of lacosamide
5. Initiate treatment and stabilise dose of lacosamide
6. Review the patient's condition and monitor response to treatment regularly
7. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
8. Report serious adverse events to the MHRA
9. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)

General Practitioner responsibilities					
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days					
2. Prescribe lacosamide at the dose recommended					
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement					
GP Prescribing System	Read Code	Description	GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing	SystemOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist					
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment					
6. Refer back to specialist if condition deteriorates					
7. Report serious adverse events to specialist and MHRA					
8. Stop treatment on advice of specialist					

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Share any concerns in relation to treatment with lacosamide with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking lacosamide
4. Attend regular outpatient appointments with the specialist

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Indication	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy	
Dosage and Administration	<p>Lacosamide must be taken twice a day.</p> <p>The recommended starting dose is 50 mg twice a day which should be increased to an initial therapeutic dose of 100 mg twice a day after one week.</p> <p>Depending on response and tolerability, the maintenance dose can be further increased by 50 mg twice a day every week, to a maximum recommended daily dose of 400 mg (200 mg twice a day).</p> <p>Lacosamide may be taken with or without food.</p> <p>In accordance with current clinical practice, if lacosamide has to be discontinued, it is recommended this be done gradually (e.g. taper the daily dose by 200 mg/week).</p>	
Renal Impairment	Mild or moderate renal impairment (CL _{CR} > 30ml/min)	<p>No dose adjustment is necessary in mildly and moderately renally impaired patients</p> <p>A loading dose of 200 mg may be considered, but further dose titration (>200 mg daily) should be performed with caution.</p>
	Severe (CL _{CR} ≤30 ml/min)	<p>A maximum maintenance dose of 250 mg/day is recommended</p> <p>In these patients, the dose titration should be performed with caution. If a loading dose is indicated, an initial dose of 100 mg followed by a 50 mg twice daily regimen for the first week should be used</p>
	Endstage renal disease	<p>Treatment of patients with end-stage renal disease should be made with caution as there is little clinical experience and accumulation of a metabolite (with no known pharmacological activity).</p>
	Patients requiring haemodialysis	<p>A supplement of up to 50% of the divided daily dose directly after the end of haemodialysis is recommended</p>
Hepatic impairment	Mild	<p>A maximum maintenance dose of 300mg/day is recommended.</p>
	Moderate	<p>Dose titration should be performed with caution considering co-existing renal impairment. A loading dose of 200mg may be considered, but further dose titration (>200mg daily) should be performed with caution.</p>
	Severe	<p>Lacosamide has not been evaluated</p>
Contra-indications / Special precautions	Please refer to SPC	
Side Effects	Please refer to SPC	
Monitoring	<p>Dizziness</p> <p>Suicidal ideation and behaviour</p> <p>Symptoms of cardiac arrhythmia</p>	
Drug interaction	Please refer to SPC	

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

References

[Vimpat SmPC](#)

Lacosamide BNF

[NICE CG137 Epilepsies: the diagnosis and management](#)

Appendix 1:

Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (BSSE APC)

Lacosamide ESCA

Date: March 2020

Review date: March 2023

Effective Shared Care Agreement (ESCA)

Lacosamide

For the treatment of Lacosamide as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Hospital Specialist/Consultant

Name (please print) _____ Signature _____ Date _____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with (*drug name*) for (*indication*)

General Practitioner

Name (please print) _____ Signature _____ Date _____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.						
GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystemOne	XaB58	Shared care