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 confident 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		SystmOne	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

BACK-UP ADVICE AND SUPPORT

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

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	Lacosamide must be taken twice a day. 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. 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). Lacosamide may be taken with or without food. 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).	
Renal Impairment	Mildly and moderately renally impaired patients (CL_{CR} >30 ml/min)	No dose adjustment is necessary in mildly and moderately renally impaired patients
	Mild or moderate renal impairment	A loading dose of 200 mg may be considered, but further dose titration (>200 mg daily) should be performed with caution
	Severe (CL_{CR} ≤30 ml/min)	A maximum maintenance dose of 250 mg/day is recommended 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
	Endstage renal disease	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).
	Patients requiring haemodialysis	A supplement of up to 50% of the divided daily dose directly after the end of haemodialysis is recommended
Hepatic impairment	Mild	No dose adjustment is needed
	Moderate	
	Severe	Lacosamide has not been evaluated
Contra-indications / Special precautions	**Contraindication:-** Hypersensitivity to the active substance or to any of the excipients listed Known second- or third-degree atrioventricular (AV) block. **Cautions:-** <u>Dizziness</u> Treatment with lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine . <u>Cardiac Rhythm and Conduction</u> Prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Caution should especially be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when lacosamide is used in combination with products known to be associated with PR prolongation. Second degree or higher AV block has been reported in post-marketing experience. In the placebo-controlled trials of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy trials and in post-marketing experience. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counselled to seek medical advice should any of these symptoms occur. <u>Suicidal ideation and behaviour</u> Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lacosamide. Therefore 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.	

	Syrup: Lacosamide syrup contains sodium methylhydroxybenzoate (E219), which may cause allergic reactions (possibly delayed). It contains 3.7 g sorbitol (E420) per dose (200 mg lacosamide), corresponding to a calorific value of 9.7 kcal. Patients with rare hereditary problems of fructose intolerance should not take this medicine. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. It contains 1.24 mmol (or 28.36 mg) sodium per dose (200 mg lacosamide). To be taken into consideration for patients on a controlled sodium diet.	
Side Effects	Very common	Dizziness, headache, diplopia, nausea
	Common	Depression, confusional state, insomnia, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, paraesthesia, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhoea, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, feeling drunk, fall, skin laceration, contusion
Monitoring	Dizziness	

Drug interaction (significant interaction as outlined in BNF, please see BNF and SPC for more detail)

Lacosamide belongs to **Antiepileptics** and will have the following interactions:

Antidepressants, SSRI	anticonvulsant effect of antiepileptics antagonised by SSRIs(convulsive threshold lowered)
Antidepressants, Tricyclic	anticonvulsant effect of antiepileptics antagonised by tricyclics (convulsive threshold lowered)
Antidepressants, Tricyclic (related)	anticonvulsant effect of antiepileptics possibly antagonised by tricyclic-related antidepressants(convulsive threshold lowered)
Antipsychotics	anticonvulsant effect of antiepileptics antagonised by antipsychotics (convulsive threshold lowered) **Note:** Increased risk of toxicity with myelosuppressive drugs
Mefloquine	anticonvulsant effect of antiepileptics antagonised by mefloquine
Orlistat	possible increased risk of convulsions when antiepileptics given with orlistat

References

Lacosamide SmPC
Lacosamide BNF
NICE CG137 The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care

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I agree to participate in this shared care agreement for the treatment of the below named patient with 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.

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

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

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