Effective Shared Care Agreement (ESCA)

Eslicarbazepine acetate tablets

For the adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients over 18 years of age.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of eslicarbazepine acetate tablets for epileptic seizures 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 not obliged 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. Confirm the patient has used oxcarbazepine (at maximum tolerated dose) or has documentation of intolerance.
3. Perform baseline assessment and periodic review of renal and hepatic function (as indicated for each patient).
4. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
5. 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.
6. Initiate treatment and stabilise dose of eslicarbazepine acetate tablets.
7. Review the patient's condition and monitor response to treatment regularly. If the patient becomes seizure free then providing there is a channel of communication between the specialist and GP, the specialist does not need to see the patient again.
8. Send a written summary promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
9. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
10. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Ensure that the patient has used oxcarbazepine (at maximum tolerated dose) or has documentation of intolerance.						
3. Adjust the dose as advised by the specialist.						
4. 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
5. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist.						
6. 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.						
7. Refer back to specialist if condition deteriorates.						
8. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
9. Stop treatment on advice of specialist or initiate tapered withdrawal if advised to do so.						

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 eslicarbazepine acetate tablets with the specialist, clinical nurse specialist or GP.
3. Report any adverse effects e.g. mood swings to the specialist or GP whilst taking eslicarbazepine acetate tablets.
4. Attend regular outpatient appointments with the specialist.

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

SUPPORTING INFORMATION

Indication	Adjunctive treatment for partial-onset seizures with or without secondary generalisation in patients over 18 years of age. Eslicarbazepine acetate tablets should only be considered following referral to a tertiary care specialist in line with NICE CG 137, and after oxcarbazepine has been tried.	
Dosage and Administration	Eslicarbazepine acetate tablets must be added to existing anticonvulsant therapy and the dose should be titrated on the basis of clinical effect. The recommended starting dose is 400 mg once daily which should be increased to 800 mg once daily after one or two weeks. Based on individual response, the dose may be increased to 1200 mg once daily.	
Renal Impairment	Mild eGFR >60 mL/min/1.73 m^2:	No dose adjustment required.
	Moderate eGFR 30–60 mL/min/1.73 m^2:	Reduce initial dose to 200mg once daily OR 400 mg every other day for 2 weeks then 400 mg once daily. However, based on individual response, the dose may be increased.
	Severe eGFR <30 mL/min/1.73 m^2:	Use is not recommended in patients with severe renal impairment due to insufficient data.
Hepatic impairment	Mild	No dose adjustment is needed
	Moderate	
	Severe	Not recommended.
Contra-indications / Special precautions	**Contra-Indications:** • Hypersensitivity to eslicarbazepine acetate tablets, to other carboxamide derivatives (e.g. carbamazepine, oxcarbazepine) or to any of the excipients. • Known second or third degree atrioventricular (AV) block. **Cautions:** • Suicidal ideation and behaviour have been reported in patients treated with antiepileptic active substances in several indications. Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. • Eslicarbazepine acetate has been associated with some central nervous system adverse reactions, such as dizziness and somnolence, which could increase the occurrence of accidental injury. • Rash developed as an adverse reaction in 1.2% of patients treated with eslicarbazepine acetate tablets in placebo-controlled add-on studies in epileptic patients. If signs or symptoms of hypersensitivity develop, eslicarbazepine acetate tablets must be discontinued. • Patients who are positive for the HLAB*1502 allele may be at risk for developing Stevens Johnson syndrome (SJS) after treatment with eslicarbazepine acetate tablets. The prevalence of HLA-B*1502 carrier is about 10% in Han Chinese and Thai populations. These individuals should be screened for this allele before starting treatment. • Hyponatraemia has been reported as an adverse reaction in 1.5% of patients treated with eslicarbazepine acetate tablets. Frequency of hyponatraemia increased with increasing eslicarbazepine acetate tablets dose. In patients with pre-existing renal disease leading or in patients concomitantly treated with medicinal products which may themselves lead to hyponatraemia, serum sodium levels should be examined before and during treatment with eslicarbazepine acetate tablets. If clinically relevant hyponatraemia develops, eslicarbazepine acetate tablets should be discontinued. • Prolonged PR intervals have been observed in clinical studies with eslicarbazepine acetate. Caution should be exercised in patients with medical conditions or when taking concomitant medicinal products known to be associated with PR prolongation. Please refer to eslicarbazepine acetate tablets SPC for further information on warnings and precautions for use.	
Side Effects	Very common	Dizziness, somnolence.
	Common	Hyponatraemia, decreased appetite, insomnia, headache, disturbance in attention, tremor, ataxia, balance disorder, diplopia, vision blurred, vertigo, nausea, vomiting, diarrhoea, rash, fatigue, gait disturbance and asthenia.

Monitoring	Pre-treatment assessment	Monitor renal and hepatic function to guide dosage.
	After commencing treatment	No routine biochemical monitoring is required. Serum sodium levels may need to be assessed if clinically indicated (see under hyponatraemia in cautions). Monitoring of seizure control and referral to specialist in the event of unsatisfactory control. Monitor for signs of suicidal ideation and behaviours.

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

Eslicarbazepine has the following interaction information:

Agent	Severity of interaction:	Evidence for interaction:	Notes
Combined hormonal contraceptives	Severe	Study	Eslicarbazepine is predicted to decrease the efficacy of combined hormonal contraceptives.
Desogestrel	Severe	Theoretical	Eslicarbazepine is predicted to decrease the efficacy of desogestrel.
Etonogestrel	Severe	Theoretical	Eslicarbazepine is predicted to decrease the efficacy of etonogestrel.
Levonorgestrel	Severe	Theoretical	Eslicarbazepine is predicted to decrease the efficacy of levonorgestrel. For FSRH guidance, see Contraceptives, interactions.
Norethisterone	Severe	Anecdotal	Eslicarbazepine is predicted to decrease the efficacy of norethisterone.
Ulipristal	Severe	Anecdotal	Eslicarbazepine decreases the efficacy of ulipristal.
Fosphenytoin	Moderate	Study	Eslicarbazepine increases the exposure to fosphenytoin and fosphenytoin decreases the exposure to eslicarbazepine. Manufacturer advises monitor and adjust dose.
Carbamazepine	Moderate	Study	Carbamazepine slightly decreases the exposure to eslicarbazepine. Manufacturer advises monitor and adjust dose.
Phenytoin	Moderate	Study	Eslicarbazepine increases the exposure to phenytoin and phenytoin decreases the exposure to eslicarbazepine. Manufacturer advises monitor and adjust dose.
Simvastatin	Moderate	Study	Eslicarbazepine moderately decreases the exposure to simvastatin. Manufacturer advises monitor and adjust dose.
Atorvastatin	Moderate	Theoretical	Eslicarbazepine is predicted to decrease the exposure to atorvastatin. Manufacturer advises monitor and adjust dose.
Hormone replacement therapy	Moderate	Anecdotal	Eslicarbazepine is predicted to decrease the effects of Hormone replacement therapy.

References

1. Summary of Product Characteristics (Zebinix®) Eisai Ltd. Accessed Nov 2017.
2. NICE CG 137. Epilepsies: diagnosis and management. January 2012.
3. BNF online

Appendix 1:

Effective Shared Care Agreement (ESCA)

Eslicarbazepine acetate tablets

For the adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients over 18 years of age

To be completed by Specialist team

Confirm the patient	Please tick	Dose of oxcarbazepine
Has used oxcarbazepine (at maximum tolerated dose)	☐	
or		
Has documentation of intolerance.	☐	

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 eslicarbazepine acetate tablets for the adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients over 18 years of age.

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		SystmOne	XaB58	Shared care