Effective Shared Care Agreement (ESCA)

# Eslicarbazepine acetate

**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 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** |
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| 1. Confirm the diagnosis of epilepsy. |
| 2. Confirm the patient has used oxcarbazepine (at maximum tolerated dose) or has documentation of intolerance. |
| 3. Obtain approval via Trust's DTC (or equivalent decision making body) before eslicarbazepine acetate is initiated. Please complete details on page 3. |
| 4. Perform baseline assessment and periodic review of renal and hepatic function (as indicated for each patient). |
| 5. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient. |
| 6. 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. |
| 7. Initiate treatment and stabilise patient on maintenance dose of eslicarbazepine acetate. |
| 8. 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. |
| 9. Send a written summary promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay. |
| 10. Report serious adverse events to the MHRA. |
| 11. Ensure clear backup arrangements exist for GPs, for advice and support. |

| **General Practitioner responsibilities** |
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| 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. Ensure that the requesting consultant has obtained approval via Trust's DTC (or equivalent decision making body) before eslicarbazepine acetate is initiated. (Please see page 3 for details) |
| 4. Prescribe eslicarbazepine acetate at the dose recommended. |
| 5. 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 |

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| 6. Monitor the patient's response to treatment; make dosage adjustments if agreed with specialist. |
| 7. Report to and seek advice from the specialist or clinical nurse specialist if the condition deteriorates or on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment. |
| 8. Report serious adverse events to the specialist and MHRA. |
| 9. Stop treatment on advice of the specialist or initiate tapered withdrawal if advised to do so. |

| **Patient's role** |
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| 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 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. |
| 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**

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| **Indication** | Adjunctive treatment for partial-onset seizures with or without secondary generalisation in patients over 18 years of age. Eslicarbazepine acetate 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 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.<br><br>Based on individual response, the dose may be increased to 1200 mg once daily. | |
| **Renal Impairment** | Mild<br>eGFR >60 mL/min/1.73 $m^2$: | No dose adjustment required. |
| | Moderate<br>eGFR 30–60 mL/min/1.73 $m^2$: | Reduce initial dose to 400 mg every other day for 2 weeks then 400 mg once daily. However, based on individual response, the dose may be increased. |
| | Severe<br>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 / Cautions** | **Contra-Indications:**<br>• Hypersensitivity to eslicarbazepine acetate, to other carboxamide derivatives (e.g. carbamazepine, oxcarbazepine) or to any of the excipients.<br>• Known second or third degree atrioventricular (AV) block.<br>**Cautions:**<br>• 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.<br>• Rash developed as an adverse reaction in 1.1% of patients treated with eslicarbazepine acetate in placebo-controlled add-on studies in epileptic patients. If signs or symptoms of hypersensitivity develop, eslicarbazepine acetate must be discontinued.<br>• Patients who are positive for the HLAB*1502 allele may be at risk for developing Stevens Johnson syndrome (SJS) after treatment with eslicarbazepine acetate. 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.<br>• Hyponatraemia has been reported as an adverse reaction in 1.2% of patients treated with eslicarbazepine acetate. Frequency of hyponatraemia increased with increasing eslicarbazepine acetate 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. If clinically relevant hyponatraemia develops, eslicarbazepine acetate should be discontinued.<br>• 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.<br>• Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment considered.<br>Please refer to eslicarbazepine acetate 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** | Monitor renal and hepatic function to guide dosage.<br>No routine biochemical monitoring is required. Serum sodium levels may need to be assessed if clinically indicated (see under hyponatraemia in cautions).<br>Monitoring of seizure control and referral to specialist in the event of unsatisfactory control.<br>Monitor for signs of suicidal ideation and behaviours. | |

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| **Drug interactions** (shaded agents indicate significant interactions as outlined in BNF, please see current BNF and SPC for more detail) | |

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| Carbamazepine | plasma concentration of eslicarbazepine possibly reduced by carbamazepine but risk of side-effects increased. |
| Fosphenytoin | plasma concentration of eslicarbazepine reduced by fosphenytoin , also plasma concentration of fosphenytoin increased. |
| Oestrogens | eslicarbazepine accelerates metabolism of oestrogens (reduced contraceptive effect with combined oral contraceptives, contraceptive patches, and vaginal rings—see Contraceptive Interactions in BNF). |
| Oxcarbazepine | manufacturer of eslicarbazepine advises to avoid concomitant use with oxcarbazepine |
| Phenytoin | plasma concentration of eslicarbazepine reduced by phenytoin, also plasma concentration of phenytoin increased. |
| Progestogens | eslicarbazepine accelerates metabolism of progestogens (reduced contraceptive effect with combined oral contraceptives, progestogen-only oral contraceptives, contraceptive patches, vaginal rings, etonogestrel-releasing implant, and emergency hormonal contraception—see Contraceptive Interactions in BNF). |
| Rosuvastatin | eslicarbazepine reduces plasma concentration of rosuvastatin. |
| Simvastatin | eslicarbazepine reduces plasma concentration of simvastatin —consider increasing dose of simvastatin. |
| Warfarin | eslicarbazepine reduces plasma concentration of warfarin. |

**References**


1. Summary of Product Characteristics (Zebinix®) Eisai Ltd. Accessed July 2015
2. NICE CG 137. The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. CG 137 January 2012.


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I confirm that the Trust's DTC (or equivalent) has approved the use of eslicarbazepine acetate for the below named patient.

DTC (or equivalent) Chairman Approval
Name (please print)_____Signature _____Date_____

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I agree to participate in this shared care agreement for the treatment of the below named patient with eslicarbazepine acetate for epileptic seizures

*Hospital Specialist/Consultant*
Name (please print)_____Signature_____Date_____

*General Practitioner -*
Name (please print)_____Signature _____Date_____

| Patient's name | Date of birth | Sex | Home Address | Hospital Number |
|---|---|---|---|---|
| | | | | |
| | | | | NHS Number |
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Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: