

## RELEVANT ACUTE TRUST LOGO

### WORKING IN PARTNERSHIP WITH



Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) North East Hampshire & Farnham CCG, Crawley CCG and Horsham & Mid-Sussex CCG

#### SHARED CARE PRESCRIBING GUIDELINE

Eslicarbazepine (Zebinex®) prescribed in adults for the adjunctive therapy of partial-onset (focal) seizures with or without secondary generalisation

**Prescribing Clinical Network classification: Amber in adults**  
**(Note: Eslicarbazepine is considered Red for use in children)**

N.B. The eligibility criteria included here apply to new patients commencing treatment under this guideline & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

#### NOTES to the GP

**Amber drugs:** Prescribing to be initiated by a hospital specialist (or if appropriate by a GP with specialist interest) but with the potential to transfer to primary care. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs.

The questions below will help you confirm this:

- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. Sign and return a copy of page 4 to the requesting consultant at the Acute Trust. Until the requesting consultant at the Acute Trust has received a signed copy of page 4 indicating that shared care has been agreed all care (including prescribing) remains with the consultant at the Acute Trust.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG pharmacist will assist you in making decisions about shared care.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

**The patient's best interests are always paramount**

The GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant

<b>Reason for Update:</b> New Information	<b>Prepared by:</b> Mr Jayesh Shah, Primary Care Pharmacist
<b>Valid from:</b> 07/12/2014	<b>Review date:</b> 07/12/2014
<b>Version:</b> 2.0	<b>Supersedes version:</b> 1.0
	<b>Approved by:</b>

## Information

This information sheet does not replace the [SPC](#), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the [BNF](#). **Link to the relevant SPC website:** [www.medicines.org.uk/emc/medicine/22376](http://www.medicines.org.uk/emc/medicine/22376)

Report patient safety incidents via the National Reporting System: [www.nrls.npsa.nhs.uk/home](http://www.nrls.npsa.nhs.uk/home)  
Report adverse events to the MHRA via: [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk)

**Dose:** Eslicarbazepine must be added to existing anticonvulsant therapy. Starting dose is 400mg (HALF tablet) once daily for two weeks then increased to 800mg (ONE tablet) once daily for two weeks and then subject to response to continue at this dose or increase to 1200mg (ONE and a HALF tablet) once daily.

## Cautions:

- **Elderly:** There is limited safety information on the use of eslicarbazepine in the elderly.
- **Paediatrics:** The safety and efficacy of eslicarbazepine in children and adolescents below 18 years has not yet been established.
- **Renal Impairment:** Caution should be exercised in the treatment of patients with renal impairment and the dose should be adjusted according to creatinine clearance (CL<sub>CR</sub>) as follows:
  - Stage 2: Mild (60-89ml/min): No dose adjustment required
  - Stage 3: Moderate (30-59 ml/min): Initial dose of 200mg daily or 400mg every other day
  - Stage 4: Six week monitoring of renal function: Severe (15-29ml/min): Not recommended.
- **Hepatic Impairment:** No dose adjustment is needed in patients with mild to moderate hepatic impairment. Not recommended in severe hepatic impairment due to insufficient data.

## Contraindications

- Hypersensitivity to the active substance, to other carboxamide derivatives (e.g. carbamazepine, oxcarbazepine) or to any of the excipients: povidone K 29/32, croscarmellose sodium, magnesium stearate
- Second or third degree atrioventricular (AV) block.

**Side effects:** Common side effects are gastro-intestinal disturbances, dizziness, drowsiness, headache, impaired coordination, tremor, visual disturbances, fatigue, and rash

## Mental Health including Suicidal Ideation and Behaviour:

Antiepileptic treatment is associated with a small risk of suicidal thoughts and behaviour; available data suggest that the increased risk applies to all antiepileptics and is seen as early as 1 week after starting treatment.

Patients with symptoms of depression or suicidal thoughts would benefit from switching to an alternative anticonvulsant. Patients should not stop or switch treatment on the basis of this information and without speaking to a healthcare professional.

Treatment options of which antidepressant would be suitable in epileptic patients is accessible on the Mood Hive at [www.sabp.nhs.uk/moodhive](http://www.sabp.nhs.uk/moodhive)

**Pregnancy:**

There is an increased risk of congenital abnormalities associated with the use of antiepileptic drugs.

- Risk is increased if anti-epileptics are used during the first trimester.
- Risk is increased if the patient takes two or more antiepileptic drugs

It is not recommended to use eslicarbazepine in pregnancy.

To reduce the risk of neural tube defects, folate supplementation (usually higher dose of 5mg) is advised before conception and throughout the first trimester.

Further advice should be taken from The UK Teratology Information Service [www.uktis.org](http://www.uktis.org)

**Breastfeeding:** Risk cannot be excluded; breast-feeding should be discontinued during treatment.

**Criteria for Use: RESPONSIBILITIES and ROLES**

Specialist responsibilities
<ol style="list-style-type: none"><li>1. Diagnosis (individual to shared care)</li><li>2. To assess the suitability of patient for Eslicarbazepine treatment</li><li>3. To discuss the aims, benefits and side effects of treatment with the patient as well as their role</li><li>4. Explain to the patient their treatment plan including the dosing schedule</li><li>5. Baseline monitoring undertaken specific to Eslicarbazepine.<ul style="list-style-type: none"><li>• Baseline FBC, LFTs, RF and ECG prior to starting treatment</li><li>• Repeat FBC, LFTs &amp; RF after 6 months of treatment, or earlier if clinically indicated</li><li>• Sodium monitoring pre and post therapy if elderly, pre existing renal disease or if patient also on medication that may lead to hyponatraemia (e.g. diuretic, desmopressin, SSRI)</li></ul></li><li>6. To initiate therapy by prescribing for a minimum of 3 months.</li><li>7. Communication by letter to the GP stating Eslicarbazepine has been started. Letter to request and remind GP to enter this medication on the GP clinical records as "Hospital Only" until notification provided of shared care agreement.</li><li>8. Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan</li><li>9. Patients and caregivers should be advised to be alert to any mood changes, distressing thoughts, or feelings about suicide or harming themselves at any point during treatment and advised to contact medical help if this occurs.</li><li>10. Patients should be monitored for signs of depression or suicidal thoughts and behaviour throughout treatment and should be referred for appropriate treatment if necessary</li><li>11. Discuss the treatment plan with the patient and ensure they understand the plan for their subsequent treatment</li><li>12. Discuss with females of child bearing age the risk v benefits of antiepileptic's and what action should be taken if they are considering having a child or accidentally become pregnant.</li><li>13. Discuss with all patients the risk of sudden unexpected death from epilepsy (SUDEP)</li><li>14. Inform patients to recognise signs of blood, liver or skin disorders</li><li>15. Inform patients that if symptoms such fever, rash, mouth ulcers, bruising or bleeding develop then they should seek immediate medical attention.</li><li>16. Supply GP with summary of patient review (including anticipated length of treatment) and a copy of the shared care document.</li><li>17. Advise GP if treatment is to discontinue at any point</li><li>18. Inform GP if patient does not attend planned follow-up</li></ol>

### General Practitioner responsibilities

1. GP to update clinical records when communication from secondary care received in change of therapy for patient. An entry to indicate "Hospital Only" may be initially needed. It is important for the GP to enter any new medication on to the clinical records to highlight any interactions with other current medication or future new medication.
2. Subsequent prescribing of Eslicarbazepine at the dose recommended.
3. GP to update clinical records when shared care is agreed.
4. Monitoring required for Eslicarbazepine
  - To be aware patients may present with symptoms such as fever, rash lymphadenopathy (swelling of the glands) and this may occur between 1 and 8 weeks of exposure after starting treatment. This would usually occur whilst under the care of the specialist.
  - To be aware if patients present complaining of worsening of seizures, confusion or decreased consciousness that this may be due to low sodium. Patients who are elderly, renal patients or patients on medication that may lead to hyponatraemia such as diuretic, desmopressin or SSRI are at risk. Consultant should be contacted to discuss discontinuation of eslicarbazepine.
  - To monitor U and E, FBC, LFT every 2 years if monitoring is not undertaken in secondary care or if patient discharged to primary care.
5. Eslicarbazepine is to be prescribed as the brand Zebinix

### Patient's / Carer's role

1. Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with Eslicarbazepine
3. Tell the specialist or GP of any other medication being taken, including over-the-counter products.
4. Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP
5. To seek medical advice if they develop any mood changes, distressing thoughts or feelings about suicide or harming them at any point during treatment.
6. To seek immediate medical advice if symptoms such as fever, rash, mouth ulcers, bruising or bleeding develop

### BACK-UP ADVICE AND SUPPORT

Contact details	Specialist	Telephone No.	Email address: (NHS NET)
Specialist:			
Hospital Pharmacy:			
Out of hours contact:			
For information on SUDEP and patient/carer support:		01235 772850	<a href="http://www.sudep.org">www.sudep.org</a>

AUDIT / SURVEY (to be carried out by specialist clinic)

**SHARED CARE PRESCRIBING GUIDELINE: Eslicarbazepine for the Treatment of Epilepsy.  
Agreement for transfer of prescribing to GP**

Patients Name.....  Address..... .....  DOB.....  Hospital No.....	<b>Drug name and dose: Eslicarbazepine</b>   <b>The following tests, investigations have been carried out:</b>  List any relevant tests:
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**Date initiated:**

**At the last patient review the drug appeared to be controlling symptoms/ providing benefit:**

Yes / No

**The patients has now been stabilised on a dose of: .....**

**I have discussed the risk of SUDEP (Sudden Unexpected Death in Epilepsy Patients) with the patient and family in regards to this medication.**

**I will arrange to review this patient regularly. Date of next clinic appointment:**

<b>Agreement to shared care, to be signed by GP and Consultant.</b>	
<b>Consultant Name:</b>  <b>Address:</b>  <b>Contact Number:</b>  <b>Consultants Signature:</b>  <b>Date:</b>	<b>GP Name:</b>  <b>Address:</b>  <b>Contact Number:</b>  <b>GP Signature</b>  <b>Date:</b>
<b>Main Carer:</b>  <b>Address:</b>  <b>Contact Number:</b>	<b>Key Worker:</b>  <b>Address:</b>  <b>Contact Number:</b>
<b>Hospital Pharmacist Name:</b> <b>Contact Number:</b>	If shared care is agreed and GP has signed above please return a copy of this page to the requesting consultant