

## BNSSG Shared Care Guidance

Please complete all sections

### Section 1: Heading

<b>Drug</b>	Oxcarbazepine
<b>Amber</b> <i>three months</i>	
<b>Indication</b>	Monotherapy or adjunctive therapy of focal seizures with or without secondary generalised tonic-clonic seizures in adults.

### Section 2: Treatment Schedule

<b>Usual dose and frequency of administration</b> <i>(Please indicate if this is licensed or unlicensed and any relevant dosing information)</i>	<p>Recommended initial dose of 600mg/day (8-10mg/kg/day) given in 2 divided doses.</p> <p>If required, the dose may be increased by a maximum of 600mg/day at approximately weekly intervals to achieve the desired response.</p> <p>Therapeutic response is usually seen at doses between 600mg/day and 2400mg/day.</p>
<b>Route and formulation</b>	<p>Film-coated tablets and suspension for oral administration.</p> <p>Tablets available in 150mg, 300mg and 600mg strengths. Suspension available in 60mg per ml strength.</p> <p>The originator brand name is Trileptal but generic formulations are available. The patient should be maintained on a particular manufacturer's product where possible.</p> <p>The tablets can be broken into two halves to allow for easier swallowing but the tablet cannot be divided into equal doses. The oral suspension should be used where the required dose cannot be administered using whole tablets.</p> <p>The tablets and suspension are bioequivalent.</p>
<b>Duration of treatment</b>	Indefinite, until the specialist advises otherwise.

### Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

<b>Baseline tests - where appropriate</b>
<ul style="list-style-type: none"> <li>• <b>HLA-B*1502 allele</b> testing may be considered in individuals of Han Chinese or Thai origin as its presence in these individuals has been shown to be strongly associated with the risk of severe cutaneous reactions.</li> <li>• <b>Serum sodium</b> in patients with pre-existing renal conditions associated with low sodium levels,</li> </ul>

# BNSSG Shared Care Guidance

patients treated concomitantly with sodium-lowering products (diuretics, desmopressin, NSAIDs)

**Subsequent tests - where appropriate** (*Please indicate who takes responsibility for taking bloods and interpreting results*)

Test	Frequency	Who by	Action/management
Serum sodium (in patient population described above)	2 weeks after initiation and then monthly for the first 3 months. Then as per clinical need.	Secondary care	Secondary care to adjust if required.
Liver function tests	If a hepatic event is suspected	Primary care	Hepatitis can occur very rarely. Liver function should be evaluated if this is suspected. Discontinuation may be required. Contact secondary care for advice.

## Section 4: Side Effects

*Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.*

<b>Side effects and management</b>	Side effect	Frequency/severity	Action/management
	Suicidal ideation/behaviour	Uncommon	Seek specialist advice.
	Hepatitis	Very rare	Evaluate liver function if suspected. Seek urgent advice from specialist team. Discontinuation or reduction may be required.
	Haematological disorders ( <i>Agranulocytosis, aplastic anaemia, pancytopenia</i> )	Not known	Discontinue medication if severe. Seek advice from specialist team.
	Serious dermatological reactions ( <i>includes Stevens-Johnson syndrome and toxic epidermal necrolysis</i> )	Very rare	Discontinue and seek urgent advice from specialist team.
	Hyponatraemia	Common	Seek advice from specialist team if symptomatic as dose adjustment may be required.
<b>Referral back to specialist</b>	<ul style="list-style-type: none"> <li>• Any patient experiencing unmanageable side effects.</li> <li>• Any patient that is pregnant or considering pregnancy.</li> <li>• Any patients showing signs of suicidal ideation.</li> <li>• Please refer back to secondary care if advice is needed for unmanaged seizures.</li> <li>• Where patients require discontinuation of therapy due to side effects or other reasons please refer back to secondary care.</li> </ul>		

## Section 5: Other Issues

**(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)**

*Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)*

<b>Issues</b>	<u>Drug interactions</u>
	<ul style="list-style-type: none"> <li>• <b>CYP3A4 and CYP3A5 induction</b> – Oxcarbazepine is a weak inducer of CYP 3A4/3A5 which is responsible for many medicines (e.g. immunosuppressants, other antiepileptics),</li> <li>• <b>Hormonal contraceptives:</b> Oxcarbazepine can render hormonal contraceptives</li> </ul>

# BNSSG Shared Care Guidance

	<p>ineffective. Non-hormonal forms are recommended instead.</p> <ul style="list-style-type: none"> <li>• <b>CYP2C19 inhibition</b> – interactions can arise when oxcarbazepine is administered with medicines metabolised by CYP2C19 (e.g. phenytoin)</li> <li>• Anticonvulsant effect of antiepileptics reduced by SSRIs, tricyclics, monoamine oxidase inhibitors, antipsychotics, orlistat, mefloquine.</li> </ul> <p><b><u>Contraindications</u></b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity to active substance or any of the excipients.</li> </ul> <p><b><u>Cautions</u></b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity to carbamazepine – 25-30% of these individuals may experience hypersensitivity to oxcarbazepine.</li> <li>• Increased risk of suicidal thoughts and behaviour. Encourage patient to report these if they occur.</li> </ul> <p><b><u>Pregnancy</u></b></p> <ul style="list-style-type: none"> <li>• Effective antiepileptic therapy should not be interrupted but a moderate teratogenic risk cannot be excluded due to limited amount of data available.</li> <li>• Any woman who falls pregnant or wishes to conceive should be referred back to the specialist team.</li> </ul> <p><b><u>Renal impairment</u></b></p> <ul style="list-style-type: none"> <li>• <b>Mild/moderate impairment</b> (CrCl &gt; 30ml/min) - No dose adjustment required.</li> <li>• <b>Severe impairment</b> (CrCl ≤30 ml/min) – Initiate at half the usual dose (300mg/day) and increase, in at least weekly intervals, to achieve the desired clinical response.</li> </ul> <p><b><u>Hepatic impairment</u></b></p> <ul style="list-style-type: none"> <li>• <b>Mild/moderate impairment</b> – No dose adjustment required.</li> <li>• <b>Severe impairment</b> – not studied, use with caution.</li> </ul>
<b>Reminder to ask patient about specific problems</b>	Signs of suicidal ideation/behaviour

## Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Please discuss with specialist team if you become pregnant or wish to conceive.
2. Patients should be encouraged to seek medical advice should any signs of suicidal ideation or behaviour emerge.
3. Discontinuation should be performed on the advice of a medical professional, do not abruptly discontinue oxcarbazepine.
4. Patients should be advised not to drive or operate machinery if they experience dizziness or blurred vision which may affect their ability to perform such activities.

## Section 7: Generic principles of shared care for SECONDARY CARE

### Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1**.
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3**.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.

# BNSSG Shared Care Guidance

6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1**.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5**.

## Section 8: Generic principles of shared care for PRIMARY CARE

### Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1**.
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1**.
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5**.

## Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Consultant Neurologist managing patient	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Neurology Registrar on call	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Neurosciences specialist pharmacist(s)	North Bristol NHS Trust	Via switchboard (0117 9505050)	
Amelia Gregory (Epilepsy Specialist Nurse)	North Bristol NHS Trust	Via switchboard (0117 9505050)	Amelia.Gregory@nbt.nhs.uk
Helen Hodgson (Epilepsy Specialist Nurse)	North Bristol NHS Trust	Via switchboard (0117 9505050)	Helen.Hodgson@nbt.nhs.uk

## Section 11: Document Details

Date prepared	October 2011 Updated May 2019
Prepared by	Kirsty Brisker (Lead Neurosciences Specialist Pharmacist) Updated by Gemma Bray (Neurosciences Specialist Pharmacist)
Date approved by JFG	15 <sup>th</sup> October 2019
Date of review	October 2021
Document Identification: Version	Oxcarbazepine SCP Update May 2019 v2

# BNSSG Shared Care Guidance

## Section 12: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Draft has been circulated to relevant parties within the local area

## Section 13: References

Please list references

1. Summary of Product Characteristics for Triptal Film-coated Tablets. Accessed via [www.medicines.org.uk](http://www.medicines.org.uk). Date accessed: 10-April-2019
2. British National Formulary [online]. Accessed via [www.medicinescomplete.com](http://www.medicinescomplete.com). Date accessed 10-April-2019