Effective Shared Care Agreement (ESCA)

Zonisamide *(Zonegran®)*

ESCA: For the adjunctive treatment of partial epileptic seizures

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of zonisamide for epileptic seizures can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel competent 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 zonisamide
5. Initiate treatment and stabilise dose of zonisamide
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 zonisamide 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 zonisamide with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking zonisamide
4. Attend regular outpatient appointments with the specialist

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

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td>• monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy
• adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adults, adolescents, and children aged 6 years and above.</td></tr>
<tr><td>Dosage and Administration</td><td><u>Adults – recommended dosage escalation and maintenance regimen</u>
<table>
<tr><th>Treatment Regimen</th><th colspan="3">Titration Phase</th><th>Usual Maintenance Dose</th></tr>
<tr><td rowspan="2">Monotherapy - Newly diagnosed adult patients</td><td>Week 1 + 2</td><td>Week 3 + 4</td><td>Week 5 + 6</td><td rowspan="2">300 mg per day (once a day).
If a higher dose is required: increase at two-weekly intervals in increments of 100 mg up to a maximum of 500 mg.</td></tr>
<tr><td>100 mg/day (once a day)</td><td>200 mg /day (once a day)</td><td>300 mg / day (once a day)</td></tr>
<tr><td rowspan="2">Adjunctive therapy - with CYP3A4-inducing agents</td><td>Week 1</td><td>Week 2</td><td>Week 3 to 5</td><td rowspan="2">300 to 500 mg per day (once a day or two divided doses).</td></tr>
<tr><td>50 mg/day (in two divided doses)</td><td>100 mg /day (in two divided doses)</td><td>Increase at weekly intervals in increments of 100 mg</td></tr>
<tr><td rowspan="2">- without CYP3A4-inducing agents; or with renal or hepatic impairment</td><td>Week 1 + 2</td><td>Week 3 + 4</td><td>Week 5 to 10</td><td rowspan="2">300 to 500 mg per day (once a day or two divided doses).
Some patients may respond to lower doses.</td></tr>
<tr><td>50 mg/day (in two divided doses)</td><td>100 mg / day (in two divided doses)</td><td>Increase at two-weekly intervals in increments of up to 100 mg</td></tr>
</table></td></tr>
<tr><td>Renal Impairment</td><td>Caution must be exercised in treating patients with renal impairment, as there is limited information on use in such patients and a slower titration of zonisamide might be required. Since zonisamide and its metabolites are excreted renally, it should be discontinued in patients who develop acute renal failure or where a clinically significant sustained increase in serum creatinine is observed.</td></tr>
<tr><td>Hepatic impairment</td><td>Use in patients with hepatic impairment has not been studied. Therefore use in patients with severe hepatic impairment is not recommended. Caution must be exercised in treating patients with mild to moderate hepatic impairment, and a slower titration of zonisamide may be required.</td></tr>
<tr><td>Contra-indications / Special precautions</td><td>Please refer to SPC</td></tr>
<tr><td>Side Effects</td><td>Please refer to SPC</td></tr>
<tr><td>Monitoring</td><td>Urea, electrolytes
Liver function
Renal function
Monitoring of pancreatic lipase and amylase levels
Suicidal ideation and behaviour
Monitoring of serum bicarbonate levels
Monitoring of serum creatine phosphokinase and aldolase levels</td></tr>
<tr><td>Drug Interactions</td><td>Please refer to SPC</td></tr>
</table>

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

References

Zonisamide SmPC
Zonisamide BNF
NICE CG 137 - Epilepsies: diagnosis and management

Appendix 1:

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Zonisamide

For the adjunctive treatment of partial epileptic seizures

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 *(drug name)* for *(indication)*

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
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