Vigabatrin

ESCA: For use in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of vigabatrin for epilepsy 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 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 vigabatrin
5. Initiate treatment and stabilise dose of vigabatrin
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 vigabatrin 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 vigabatrin with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking vigabatrin
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

Indication	Treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated.
Dosage and Administration	Maximal efficacy is usually seen in the 2- 3g/day range. A starting dose of 1g daily should be added to the patient's current antiepileptic medicinal product regimen. The daily dose should then be titrated in 0.5g increments at weekly intervals depending on clinical response and tolerability. The highest recommended dose is 3g/day.
Renal Impairment	Caution should be exercised when administering the drug to older people and more particularly in patients with creatinine clearance less than 60 ml/min. Adjustment of dose or frequency of administration should be considered. Such patients may respond to a lower maintenance dose. Patients should be monitored for undesirable effects such as sedation or confusion
Contra-indications / Special precautions	**Contra-indications** Hypersensitivity to vigabatrin or to any of the excipients listed **Cautions** <u>Visual Field Defects (VFD)</u> Visual field defects (VFD) have been reported in patients receiving vigabatrin with a high prevalence (about 1/3 of patients). The onset is usually after months to years of vigabatrin therapy. The degree of visual field restriction may be severe and this may have practical consequences for the patient. Most of the patients with perimetry-confirmed defects have been asymptomatic. Hence, this undesirable effect can only be reliably detected by systematic perimetry which is usually possible only in patients with a developmental age of more than 9 years. A specifically developed method based on field specific Visual Evoked Potentials (VEP) is available from the company on request to test the presence of peripheral vision in children aged 3 years and above. At present this method has not been validated in the detection of vigabatrin attributed visual field defects. Electroretinography may be useful but should be used only in adults who are unable to cooperate with perimetry or in the very young. Available data suggests that visual field defects are irreversible even after discontinuation of vigabatrin. A deterioration of VFD after the treatment is discontinued cannot be excluded. Therefore, vigabatrin should only be used after a careful assessment of the balance of benefits and risk compared with alternatives. Vigabatrin is not recommended for use in patients with any pre-existing clinically significant visual field defect. Patients should undergo systematic screening examination when starting vigabatrin and at regular intervals for detection of visual field defects. Visual field testing should continue at 6 month intervals for the whole duration of treatment. Vigabatrin should not be used concomitantly with other retinotoxic drugs. <u>Neurological and psychiatric conditions</u> In view of the results of the animal safety studies, it is recommended that patients treated with vigabatrin are closely observed for adverse effects on neurological function. Rare reports of encephalopathic symptoms such as marked sedation, stupor and confusion in association with non-specific slow wave activity on electroencephalogram have been described soon after the initiation of vigabatrin treatment. Risk factors for the development of these reactions include higher than recommended starting dose, faster dose escalation at higher steps than recommended, and renal failure. These events have been reversible following dose reduction or discontinuation of vigabatrin. Movement disorders including dystonia, dyskinesia and hypertonia, have been reported in patients treated for infantile spasms. The benefit/risk of vigabatrin should be evaluated on an individual patient basis. If new movement disorders occur during treatment with vigabatrin, consideration should be given to dose reduction or a gradual discontinuation of treatment. As with other antiepileptic medicinal products some patients may experience an increase in seizure frequency or the onset of new types of seizures with vigabatrin. These phenomena may also be the consequence of an overdose, a decrease in plasma concentrations of concomitant antiepileptic treatment, or a paradoxical effect. As with other antiepileptic medicinal products, abrupt withdrawal may lead to rebound seizures. If a patient is to be withdrawn from vigabatrin treatment, it is recommended that this is done by gradual dose reduction over a 2- to 4-week period. Vigabatrin should be used with caution in patients with a history of psychosis, depression or behavioural problems. Psychiatric events (e.g., agitation, depression, abnormal thinking, paranoid reactions) have been reported during vigabatrin treatment. These events occurred in patients with

<table>
<tr><td></td><td colspan="2">and without a psychiatric history, and were usually reversible when vigabatrin doses were reduced or gradually discontinued.
<u>Suicidal ideation and behaviour</u>
Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. Therefore, patients should be monitored for signs of suicidal ideation and behaviour, and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice immediately should signs of suicidal ideation or behaviour emerge.</td></tr>
<tr><td rowspan="2">Side Effects</td><td>Very common</td><td>Somnolence, visual field defect, arthralgia, fatigue</td></tr>
<tr><td>Common</td><td>Anaemia, agitation, aggression, nervousness, depression, paranoid reaction, speech disorder, headache, dizziness, paraesthesia, disturbance in attention and memory impairment, mental impairment (thought disturbance), tremor, vision blurred, diplopia, nystagmus, nausea, vomiting, abdominal pain, oedema, irritability, weight increased</td></tr>
<tr><td>Monitoring</td><td colspan="2">Visual field testing
Suicidal ideation and behaviour
Renal function</td></tr>
<tr><td>Drug Interactions</td><td colspan="2">
Vigabatrin has the following interaction information:
<table>
<tr><td>Fosphenytoin</td><td>vigabatrin reduces plasma concentration of fosphenytoin</td></tr>
<tr><td>Phenytoin</td><td>vigabatrin reduces plasma concentration of phenytoin</td></tr>
</table>
Vigabatrin belongs to Antiepileptics and will have the following interactions:
<table>
<tr><td>Antidepressants, SSRI</td><td>anticonvulsant effect of antiepileptics antagonised by SSRIs (convulsive threshold lowered)</td></tr>
<tr><td>Antidepressants, Tricyclic</td><td>anticonvulsant effect of antiepileptics antagonised by tricyclics (convulsive threshold lowered)</td></tr>
<tr><td>Antidepressants, Tricyclic (related)</td><td>anticonvulsant effect of antiepileptics possibly antagonised by tricyclic-related antidepressants(convulsive threshold lowered)</td></tr>
<tr><td>Antipsychotics</td><td>anticonvulsant effect of antiepileptics antagonised by antipsychotics (convulsive threshold lowered)

Note: Increased risk of toxicity with myelosuppressive drugs</td></tr>
<tr><td>MAOIs</td><td>anticonvulsant effect of antiepileptics possibly antagonised by MAOIs (convulsive threshold lowered)

Note: For interactions of reversible MAO-A inhibitors (RIMAs) see Moclobemide, and for interactions of MAO-B inhibitors see Rasagiline and Selegiline; the antibacterial Linezolid is a reversible, non-selective MAO inhibitor</td></tr>
<tr><td>Mefloquine</td><td>anticonvulsant effect of antiepileptics antagonised by mefloquine</td></tr>
<tr><td>Orlistat</td><td>possible increased risk of convulsions when antiepileptics given with orlistat</td></tr>
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References

Vigabatrin SmPC
Vigabatrin BNF
NICE CG 137 - The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care

I agree to participate in this shared care agreement for the treatment of the below named patient with vigabatrin for epilepsy

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: