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 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 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

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

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	**Please refer to SPC**
Side Effects	**Please refer to SPC**
Monitoring	Visual field testing Suicidal ideation and behaviour Renal function
Drug Interactions	**Please refer to SPC**

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

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

Appendix 1:

Effective Shared Care Agreement (ESCA)

Vigabatrin

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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
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care