Effective Shared Care Agreement (ESCA)

Perampanel *(Fycompa®▼)*

ESCA: For the adjunctive treatment of partial seizures with or without secondary generalisation in patients over 12 years of age

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of perampanel for epileptic seizures 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 epileptic seizures 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 epileptic seizures
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 perampanel
5. Initiate treatment and stabilise dose of perampanel
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 perampanel 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 perampanel with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking perampanel
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	Adjunctive treatment for partial seizures with or without secondary generalisation in patients over 12 years of age	
Dosage and Administration	Perampanel at doses of 4 mg/day to 12 mg/day has been shown to be effective therapy in partial onset seizures. Treatment with perampanel should be initiated with a dose of 2 mg/day. The dose may be increased based on clinical response and tolerability by increments of 2 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 4 mg/day to 8 mg/day. Depending upon individual clinical response and tolerability at a dose of 8 mg/day, the dose may be increased by increments of 2 mg/day to 12 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of perampanel should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of perampanel should be titrated no more frequently than at 1-week intervals.	
Renal Impairment	Mild	No dose adjustment is required
	Moderate	Not recommended
	Severe	
Hepatic impairment	Mild	Dose increases in patients with mild and moderate hepatic impairment should be based on clinical response and tolerability. For patients with mild or moderate hepatic impairment, dosing can be initiated at 2 mg. Patients should be up-titrated using 2 mg doses no faster than every 2 weeks based on tolerability and effectiveness. Perampanel dosing for patients with mild and moderate impairment should not exceed 8 mg
	Moderate	
	Severe	Not recommended
Contra-indications / Special precautions	**Contraindication:-** Hypersensitivity to the active substance or to any of the excipients listed **Cautions:-** <u>Suicidal ideation</u> Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic medicinal products in several indications. - Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. <u>Nervous system disorders</u> Perampanel may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. <u>Oral contraceptives</u> At doses of 12 mg/day perampanel may decrease the effectiveness of progestative-containing hormonal contraceptives; in this circumstance additional non-hormonal forms of contraception are recommended when using perampanel <u>End of treatment</u> It is recommended that discontinuation be undertaken gradually to minimise the potential for rebound seizures. However, due to its long half-life and subsequent slow decline in plasma concentrations, perampanel can be discontinued abruptly if absolutely needed. <u>Falls</u> There appears to be an increased risk of falls, particularly in the elderly; the underlying reason is unclear. <u>Aggression</u> Aggressive and hostile behaviour has been reported in patients receiving perampanel therapy. In perampanel-treated patients in clinical trials, aggression, anger and irritability were reported more frequently at higher doses. Most of the reported events were either mild or moderate and patients recovered either spontaneously or with dose adjustment. However, thoughts of harming others, physical assault or threatening behaviour were observed in some patients (< 1% in perampanel clinical studies). Patients and caregivers should be counselled to alert a healthcare professional immediately if significant changes in mood or patterns of behaviour are noted. The dosage of perampanel should be reduced if such symptoms occur and should be discontinued immediately if symptoms are severe. <u>Abuse potential</u> Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of perampanel abuse. <u>Concomitant CYP 3A inducing anti-epileptic medicinal products</u> Response rates after addition of perampanel at fixed doses were less when patients received concomitant CYP3A enzyme-inducing anti-epileptic medicinal products (carbamazepine, phenytoin, oxcarbazepine) as compared to response rates in patient who received concomitant non-enzyme–inducing anti-epileptic medicinal products. Patients' response should be monitored when they are switching from concomitant non-inducer anti-epileptic medicinal products to enzyme inducing medicinal products and vice versa. Depending upon individual clinical response and tolerability, the dose may be increased or decreased 2 mg at a time.	

	Other concomitant (non- anti-epileptic) cytochrome P450 inducing or inhibiting medicinal products Patients should be closely monitored for tolerability and clinical response when adding or removing cytochrome P450 inducers or inhibitors, since perampanel plasma levels can be decreased or increased; the dose of perampanel may need to be adjusted accordingly. Perampanel contains lactose, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.	
Side Effects	Very common	Dizziness, somnolence
	Common	Decreased appetite, increased appetite, aggression, anger, anxiety, confusional state, ataxia, dysarthria, balance disorder, irritability, diplopia, vision blurred, vertigo, nausea, back pain, gait disturbance, fatigue, weight increased, fall
Monitoring	No additional monitoring required than is standard for anti-epileptic medication. As with all AEDs monitor for signs of suicidal ideation and behaviours and consider appropriate treatment Patient's response should be monitored when they are switching from concomitant non-inducer anti-epileptic medicinal products to enzyme inducing medicinal products and vice versa. Depending upon individual clinical response and tolerability, the dose may be increased or decreased 2 mg at a time.	

Drug interaction (significant interaction as outlined in BNF, please see BNF and SPC for more detail)

Perampanel has the following interaction information:

Carbamazepine	plasma concentration of perampanel reduced by carbamazepine
Fosphenytoin	plasma concentration of perampanel reduced by fosphenytoin
Oxcarbazepine	plasma concentration of perampanel reduced by oxcarbazepine
Phenytoin	plasma concentration of perampanel reduced by phenytoin
Progestogens	perampanel accelerates metabolism of progestogens (reduced contraceptive effect with combined oral contraceptives, progestogen-only oral contraceptives, contraceptive patches, vaginal rings, etonogestrel-releasing implant, and emergency hormonal contraception)

Perampanel belongs to **Antiepileptics** and will have the following interactions:

Antidepressants, SSRI	anticonvulsant effect of antiepileptics antagonised by SSRIs(convulsive threshold lowered)
Antidepressants, Tricyclic	anticonvulsant effect of antiepileptics antagonised bytricyclics (convulsive threshold lowered)
Antidepressants, Tricyclic (related)	anticonvulsant effect of antiepileptics possibly antagonised by tricyclic-related antidepressants(convulsive threshold lowered)
Antipsychotics	anticonvulsant effect of antiepileptics antagonised by antipsychotics (convulsive threshold lowered) **Note:** Increased risk of toxicity with myelosuppressive drugs
Mefloquine	anticonvulsant effect of antiepileptics antagonised by mefloquine
Orlistat	possible increased risk of convulsions when antiepileptics given with orlistat

References

Perampanel SmPC
Perampanel BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with perampanel for epileptic seizures.

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: