

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) North East Hampshire & Farnham CCG, Crawley CCG, Horsham & Mid-Sussex CCG

SHARED CARE PRESCRIBING GUIDELINE

Perampanel (Fycompa[®]) prescribed in adults for adjunctive treatment of partial onset seizures with or without secondary generalised seizures.

Prescribing Clinical Network classification: Amber in adults

N.B. The eligibility criteria included here apply to new patients commencing treatment under this guideline & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

NOTES to the GP

Amber drugs: Prescribing to be initiated by a hospital specialist (or if appropriate by a GP with specialist interest) but with the potential to transfer to primary care. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs.

The questions below will help you confirm this:

- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. Sign and return a copy of page 5 to the requesting consultant at the Acute Trust. Until the requesting consultant at the Acute Trust has received a signed copy of page 5 indicating that shared care has been agreed all care (including prescribing) remains with the consultant at the Acute Trust.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, which will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG pharmacist will assist you in making decisions about shared care.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The patient's best interests are always paramount

Reason for Update: New Information – shared care updated	Prepared by: Mr Jayesh Shah, Primary Care Pharmacist
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Version: 2.0	Supersedes version: 1.0
	Approved by: Prescribing Clinical Network on 05/11/2014
	Approved by: Prescribing Clinical Network on 01/04/2015

The GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant.

Information:

This information sheet does not replace the [SPC](#), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the [BNF](#). **Link to the relevant SPC website:** www.medicines.org.uk/emc/medicine/22376

Report patient safety incidents via the National Reporting System: www.nrls.npsa.nhs.uk/home

Report adverse events to the MHRA via: www.yellowcard.mhra.gov.uk

Dose:

Perampanel should be taken orally at bedtime. It is an adjunctive therapy.

Starting dose is at 2mg. Dose may be increased dependent on clinical response and tolerability.

Increases take place in 2mg steps; and duration of increment varies depending on other medication:

- Increase dose of perampanel no shorter than weekly if also taking Drugs (carbamazepine, oxcarbazepine, phenytoin or topiramate) that shorten the half- life of perampanel.
- Increase dose of perampanel no shorter than every two weeks if taking drugs (clobazam, clonazepam, lamotrigine, levetiracetam, phenobarbital, valproic acid and zonisamide) that do not shorten the half-life of perampanel.

Usual maintenance 4–8 mg once daily; maximum of 12 mg once daily.

Cautions:

- **Elderly:** There is limited safety information in the elderly. There appears to be an increased risk of falls in this group.
- **Paediatrics:** The safety and efficacy of perampanel in children and adolescents below 12 years has not yet been established. It is not licensed in children currently.
- **Renal Impairment:** Caution should be exercised in the treatment of patients with renal impairment and the dose should be adjusted according to creatinine clearance (CL_{CR}) as follows:
 - Stage 2: Mild (60-89ml/min):No dose adjustment required
 - Stage 3: Moderate (30-59 ml/min): Do not use
 - Stage 4: Do not use.
- **Hepatic Impairment:** Increase dose in intervals of 2 weeks and maximum dose of 8mg in patients with mild to moderate hepatic impairment. Not recommended in severe hepatic impairment.

Contraindications

- Hypersensitivity to the active substance or any of the excipients.

Side effects: Very common side effects are dizziness. Common side effects are nausea, changes in appetite, weight increase, aggression, drowsiness, dysarthria, gait disturbance, irritability, anxiety, confusion, suicidal ideation and behaviour, malaise, ataxia, back pain, vertigo and blurred vision.

Mental Health including Suicidal Ideation and Behaviour:

Antiepileptic treatment is associated with a small risk of suicidal thoughts and behaviour; available data suggest that the increased risk applies to all antiepileptics and is seen as early as 1 week after starting treatment.

Patients with symptoms of depression or suicidal thoughts would benefit from switching to an alternative anticonvulsant. Patients should not stop or switch treatment on the basis of this information and without speaking to a healthcare professional.

Treatment options of which antidepressant would be suitable in epileptic patients is accessible on the Mood Hive at www.sabp.nhs.uk/moodhive

Pregnancy:

There is an increased risk of congenital abnormalities associated with the use of antiepileptic drugs.

- Risk is increased if anti-epileptics are used during the first trimester.
- Risk is increased if the patient takes two or more antiepileptic drugs.

It is not recommended to use this medication in pregnancy.

To reduce the risk of neural tube defects, folate supplementation (usually higher dose of 5mg) is advised before conception and throughout the first trimester.

Further advice should be taken from The UK Teratology Information Service www.uktis.org

Breastfeeding: Risk cannot be excluded; breast-feeding should be discontinued during treatment. Unknown if excreted in breast milk or not.

Monitoring

Routine monitoring is required every 2 years. GP responsible when patient is stable and titrated up to correct dose. Specialists to undertake all the actions required by NICE.

Prescribing

Specialists to prescribe for first three months or until titration complete and dose stable. Specialists to prescribe until received signed copy of page 5 from the GP.

Criteria for Use: RESPONSIBILITIES and ROLES **Prescribing Clinical Network classification: Amber in adults**

Specialist responsibilities
<ol style="list-style-type: none">1. Diagnosis (Individual to shared care).2. To assess the suitability of patient for perampanel treatment.3. To discuss the aims, benefits and side effects of treatment with the patient as well as their role.4. Explain to the patient their treatment plan including the dosing schedule.5. Baseline monitoring routinely undertaken. No specific monitoring for perampanel.6. To initiate therapy and titrate to maintenance dose. Prescribing is to be for a minimum of 3 months.7. Communication by letter to the GP stating this medication has been started. Letter to request and remind GP to enter this medication on the GP clinical records as "Hospital Only" until notification provided of shared care agreement.8. Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan.9. Patients and caregivers should be advised to be alert to any mood changes, distressing thoughts, or feelings about suicide or harming themselves at any point during treatment and advised to contact medical help if this occurs.10. Patients should be monitored for signs of depression or suicidal thoughts and behaviour throughout treatment and should be referred for appropriate treatment if necessary.11. Discuss the treatment plan with the patient and ensure they understand the plan for their subsequent treatment.12. Discuss with females of child bearing age the risk v benefits of antiepileptic's and what action should be taken if they are considering having a child or accidentally become pregnant.13. Discuss with all patients the risk of sudden unexpected death from epilepsy (SUDEP).

14. Supply GP with summary of patient review (including anticipated length of treatment) and a copy of the shared care document.
15. Advise GP if treatment is to discontinue at any point.
16. Inform GP if patient does not attend planned follow-up.

General Practitioner responsibilities

1. GP to update clinical records when communication from secondary care received in change of therapy for patient. An entry to indicate "Hospital Only" may be initially needed. It is important for the GP to enter any new medication on to the clinical records to highlight any interactions with other current medication or future new medication.
2. Subsequent prescribing of perampanel at the dose recommended. Patients should not be on a titrating dose at the GP practice as this should have been managed by the consultant.
3. GP to update clinical records when shared care is agreed.
4. No specific monitoring is required for perampanel
 - To monitor U and E, FBC, LFT every 2 years if monitoring is not undertaken in secondary care or if patient discharged to primary care. (NICE Epilepsy guidelines)
5. Perampanel is to be prescribed as the brand product Fycompa.
6. If patient becomes pregnant or has become pregnant then GP to refer back to the specialist urgently. Further information may be found at www.uktis.org.

Patient's / Carer's role

1. Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with perampanel (Fycompa[®])
3. Tell the specialist or GP of any other medication being taken, including over-the-counter products.
4. Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP
5. To seek medical advice if they develop any mood changes, distressing thoughts or feelings about suicide or harming them at any point during treatment.
6. To seek immediate medical advice if symptoms such as rash occurs. If rash is mild then discontinue perampanel for a short while and then reintroduce. If rash reappears then stop.
7. If a single dose is missed then please take the next dose as normal. If more than one dose is missed please contact the doctor. The doctor can check the SPC for the latest information on what to do when a dose is missed.
8. Medication is to be taken as a single dose at bedtime. Do not crush, chew or split the tablet. The medication needs to be swallowed whole with a glass of water.
9. To order the medication in good time or have a relationship with a community pharmacist, as this medicine will have to be ordered in and will not routinely be kept on the shelf.

BACK-UP ADVICE AND SUPPORT

Contact details	Specialist	Telephone No.	Email address: (NHS NET)
Specialist:	Dr Jeff Kimber	01737 768511 Ext. 6754	Jeffery.Kimber@sash.nhs.uk
Hospital Pharmacy:	Dr Liqan Zhang	01737 768511 Ext. 2971	Liqan.Zhang@sash.nhs.uk
Surrey and Sussex Medicines Information		01737 768511 Ext 6246	MedicinesInformationPharmacists@sash.nhs.uk
Out of hours contact:		01737 768511	On Call Switchboard
For information on SUDEP and patient/carer support:		01235 772850	www.sudep.org

AUDIT / SURVEY (to be carried out by specialist clinic)

**SHARED CARE PRESCRIBING GUIDELINE: Perampanel for the Treatment of Epilepsy.
Prescribing Clinical Network classification: Amber in adults
Agreement for transfer of prescribing to GP**

Patients Name..... Address..... DOB..... Hospital No.....	Drug name and dose: The following tests, investigations have been carried out: List any relevant tests:
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Date initiated:

At the last patient review the drug appeared to be controlling symptoms/ providing benefit:
Yes / No

The patients has now been stabilised on a dose of:

I have discussed the risk of SUDEP (Sudden Unexpected Death in Epilepsy Patients) with the patient and family in regards to this medication.

I will arrange to review this patient regularly. Date of next clinic appointment:

Agreement to shared care, to be signed by GP and Consultant.	
Consultant Name: Address: Contact Number: Consultants Signature: Date:	GP Name: Address: Contact Number: GP Signature Date:
Main Carer: Address: Contact Number:	Key Worker: Address: Contact Number:
Hospital Pharmacist Name: Contact Number:	If shared care is agreed and GP has signed above please return a copy of this page to the requesting consultant