Name: Attach Banda Label here
Address:

Date of Birth:
NHS number:

Coventry & Warwickshire Area Prescribing Committee

Shared Care Agreement

Piracetam (Nootropil®▼)

SCA: Indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology, and should be used in combination with other anti-myoclonic therapies.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of piracetam for epileptic seizures can be shared between the specialist and general practitioner (GP).* GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is 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. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with epilepsy are under regular follow-up. This 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.

Specialist responsibilities
1. Initiate Piracetam and stabilise patient on initial target dose.
2. Perform baseline assessment and periodic review of renal and hepatic function (as indicated for each patient)
3. Discuss the benefits and side effects of treatment with the patient.
4. Ask the GP if he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care agreement with the patient.
5. Regular follow-up of patient (suggest at least annually). If the patient becomes seizure free then providing there is a channel of communication between the specialist and GP, the specialist does not need to see the patient again. In patients with an acute episode, spontaneous evolution may occur over time and an attempt should be made every 6 months to decrease or discontinue the medicinal treatment.
6. Communicate promptly with the GP when the treatment is changed.
7. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
8. Advise GP on dosage adjustment and when and how to stop treatment.
9. Report adverse events to MHRA.
10. Ensure that clear backup arrangements exist for GPs to obtain advice and support

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable.
2. Prescribe piracetam at the dose recommended.
3. Adjust the dose as advised by the specialist and review monitoring (see monitoring).
4. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
5. Refer patient to the specialist if his or her condition deteriorates.
6. Stop treatment on the advice of the specialist or initiate tapered withdrawal if advised to do so.
7. Monitoring of seizure control and referral to a specialist in the event of unsatisfactory control.
8. Refer adverse events to the specialist and CSM.

Patient/carer's role
1. Report to the 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 piracetam.
3. Report any adverse events e.g. mood swings to the specialist or GP whilst taking piracetam.

BACK-UP ADVICE AND SUPPORT: See patient letter and/or other supporting information for contact details of clinician(s) initiating and **stabilising** patient prior to request for shared care

This SCA should be read in conjunction with the Summary of Product Characteristics (SPC) and the current edition of the British National Formulary

SUPPORTING INFORMATION:

Licensed indications: Piracetam is licensed for patients suffering from myoclonus of cortical origin, irrespective of aetiology, and should be used in combination with other anti-myoclonic therapies.

NICE CG 137 recommends piracetam for myoclonic seizures. The guidance recommends that, if adjunctive treatment is ineffective or not tolerated, discuss with, or refer to, a tertiary epilepsy centre and consider clobazam, clonazepam, piracetam or zonisamide.

Dosage and administration: The daily dosage should begin at 7.2g increasing by 4.8g every three to four days up to a maximum of 24 g, in two or three sub-doses. Treatment with other anti-myoclonic medicinal products should be maintained at the same dosage. Depending on the clinical benefit obtained, the dosage of other such medicinal products should be reduced, if possible.

Once started, treatment with piracetam should be continued for as long as the original cerebral disease persists. In patients with an acute episode, spontaneous evolution may occur over time and an attempt should be made every 6 months to decrease or discontinue the medicinal treatment. This should be done by reducing the dose of piracetam by 1.2 g every two days (every three or four days in the case of a Lance and Adams syndrome, in order to prevent the possibility of sudden relapse or withdrawal seizures).

Elderly: Adjustment of the dose is recommended in elderly patients with compromised renal function (see 'Monitoring' below). For long term treatment in the elderly, regular evaluation of the creatinine clearance is required to allow dosage adaptation if needed.

Patients with renal impairment: The daily dose must be individualized according to renal function (see monitoring).

Patients with hepatic impairment: No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of dose is recommended as below.

Monitoring:

Baseline measurement of urea, electrolytes, and liver function. Renal and liver function should then be assessed subsequently by the GP if there are factors or conditions that suggest deterioration. The daily dose may be adjusted as follows –

Group	Creatinine clearance (ml/min)	Posology and frequency
Normal	>80	Usual daily dose, 2-4 sub doses
Mild	50-79	2/3 usual daily dose, 2 or 3 sub doses
Moderate	30-49	1/3 usual daily dose, 2 sub doses
Severe	<30	1/6 usual daily dose, 1 single intake
End-stage renal disease		Contra-indicated

Contra-indications/Cautions: Piracetam is contra-indicated in patients with severe renal impairment, hepatic impairment and to those under 16 years of age. It is also contraindicated in patients with cerebral haemorrhage, suffering from Huntington's Chorea and in those with hypersensitivity to piracetam, other pyrrolidone derivatives or any of the excipients.

Effects on platelet aggregation: Due to the effect of piracetam on platelet aggregation, caution is recommended in patients with severe haemorrhage, patients at risk of bleeding such as gastrointestinal ulcer, patients with underlying disorders of haemostasis, patients with history of haemorrhagic CVA, patients undergoing major surgery including dental surgery, and patients using anticoagulants or platelet antiaggregant drugs including low dose aspirin.

Discontinuation: Abrupt discontinuation of treatment should be avoided as this may induce myoclonic or generalised seizures in some myoclonic patients.

This product contains about 2 mmol (or about 46 mg) sodium per 24 g piracetam. To be taken into consideration by patients on a controlled sodium diet.

Side effects: Commonly reported adverse effects are nervousness, hyperkinesias, weight increase. Uncommon side effects are depression, somnolence and asthenia. See SPC for full list

Drug interactions (see also above under cautions): The drug interaction potential resulting in changes of piracetam pharmacokinetics is expected to be low because approximately 90% of the dose of piracetam is excreted in the urine as unchanged drug. *In vitro*, piracetam does not inhibit the human liver cytochrome P450 isoforms and metabolic interaction of piracetam with other drugs is unlikely.

Thyroid hormones: Confusion, irritability and sleep disorder have been reported during concomitant treatment with thyroid extract (T3 + T4).

Alcohol: Concomitant administration of alcohol had no effect on piracetam serum levels and alcohol levels were not modified by a 1.6g oral dose of piracetam**.**

Cost: At current prices, one year's treatment costs £102.39 with piracetam 24g/day (Drug Tariff, Dec 2019)

References:

1. SPC. (Nootropil®) UCB Pharma Ltd 25/1/11
2. NICE CG 137. The Epilepsies; the diagnosis and management of the epilepsies in adults and children in primary and secondary care. CG 137. January 2012.