Name: Attach Banda Label here
Address:

Date of Birth:
NHS number:

Coventry & Warwickshire Area Prescribing Committee

Shared Care Agreement

Propafenone: *for the treatment of arrhythmia in adults*

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of **propafenone** for the ***continuous*** (not intermittent) treatment of arrhythmia 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 specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Specialist Responsibilities
1. Initiate treatment with propafenone with ECG monitoring and blood pressure control (initial 1 month supply from Acute Trust Pharmacy). 2. Discuss the benefits and side effects of treatment with the patient 3. Determine whether baseline and subsequent monitoring of renal function, hepatic function and electrolytes is clinically indicated. If so, ensure adequate arrangements are in place for follow-up monitoring and that the GP is aware. *4.* Ask the GP whether he or she is willing to participate in shared care by emailing the shared care request letter, (*continue to prescribe until GP has agreed to take over prescribing).* 5. Regularly review the patient's condition and communicate promptly with the GP when treatment is changed. 6. Advise the GP on when to adjust the dose, stop treatment, or consult with the specialist. 7. Report adverse events to the MHRA and GP. 8. Ensure that clear back-up arrangements exist for GPs to obtain advice and support. 9. Explain to the patient / carer their roles Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard, and to the GP and appropriate Medicines Optimisation team.

General Practitioner Responsibilities
1. Reply to the request for shared care as soon as practicable, preferably within 2 weeks, by emailing back the shared care requesy letter. If declining the request, please indicate the reason for declining. 2. Subsequent prescribing of propafenone at the dose recommended. 3. Adjust the dose as advised by the specialist. 4. Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment. 5. Refer back to specialist if the patient's condition deteriorates. 6. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. 7. Report adverse events to the specialist and MHRA. Report adverse events to the MHRA on a Yellow Card (www.mhra.gov.uk/yellowcard), the specialist, and the appropriate Medicines Optimisation team.

Patient/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 propafenone. 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. Report any adverse effects or warning symptoms to the specialist or GP. The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card , available at pharmacies, GP surgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours). The form can also be downloaded from www.mhra.gov.uk/yellowcard

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: For the prophylaxis and treatment of ventricular arrhythmias.

Propafenone is also indicated for the prophylaxis and treatment of paroxysmal supraventricular tachyarrhythmias which include paroxysmal atrial flutter/fibrillation and paroxysmal re-entrant tachycardia's involving the AV node or accessory bypass tracts, when standard therapy has failed or is contraindicated

Dosage and administration: Initially 150 mg three times daily increasing at a minimum of three-day intervals to 300 mg twice daily and if necessary, to a maximum of 300 mg three times daily.

If the QRS interval is prolonged by more than 160msec or the PQ interval is prolonged by more than 20%, the dose should be reduced or discontinued until the ECG returns to normal limits.

The tablets should be swallowed whole and taken with a drink after food

Monitoring:
Specialist: All ECG and BP monitoring prior to initiating, and during treatment

Contraindications: Hypersensitivity to the propafenone or to any of its excipients (see SPC)

Patients with significant structural heart disease such as patients with an incident of myocardial infarction within the last 3 months, uncontrolled congestive heart failure where left ventricular output is less than 35%, cardiogenic shock (unless arrhythmia-induced), severe symptomatic bradycardia, manifest electrolyte imbalance (e.g. hyperkalemia or other potassium metabolism disorders), severe obstructive pulmonary disease or severe hypotension.

Patients with myasthenia gravis. Patients with known Brugada Syndrome

Cautions: Electrolyte disturbances should first be treated before treatment with propafenone.

It is essential that each patient given propafenone hydrochloride be evaluated electrocardiographically and clinically prior to and during therapy to determine whether the response to propafenone hydrochloride supports continued treatment.

Because of the beta-blocking effect, care should be exercised in the treatment of patients with obstructive airways disease or asthma. There is a risk of pro-arrhythmic effects, as with other anti-arrhythmics. Worsening of the ventricular arrhythmias is possible.

Brugada syndrome may be unmasked or Brugada like electrocardiogram (ECG) changes may be provoked after exposure to propafenone in previously asymptomatic carriers of the syndrome. After initiating therapy with propafenone, an ECG should be performed to rule out changes suggestive of Brugada syndrome.

For the treatment of ventricular arrhythmias, the patient should be under cardiological surveillance including ECG monitoring and blood pressure control and defibrillator facilities should be available.

Treatment stop should be considered with one of the following ECG-changes:

- QRS or QT-interval prolongation with more than 25%,
- PR-interval prolongation with more than 50%,
- QT-interval prolongation with more than 500 msec,
- or an increase in numbers or worsening of the arrhythmias

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Propafenone should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.
Breastfeeding: Propafenone is known to pass the placental barrier in humans. The concentration of propafenone in the umbilical cord has been reported to be about 30% of that in the maternal blood.

Lactation: Excretion of propafenone in human breast milk has not been studied. Limited data suggests that propafenone may be excreted in human breast milk. Propafenone should be used with caution in nursing mothers.

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Side effects: The most frequent and very common adverse reactions related to propafenone therapy are dizziness, cardiac conduction disorders and palpitations. Refer to SPC for full side-effect profile

Propafenone does not have black triangle (▼) status. All serious suspected adverse reactions (even well recognised or causal link uncertain) should be reported to the MHRA.

Drug interactions (see also above under cautions)

Local anaesthetics: Concomitant use of propafenone hydrochloride and intravenous lidocaine has been reported to increase the risks of central nervous system side effects of lidocaine.

Increased plasma levels and/or blood levels of propranolol, metoprolol, desipramine, ciclosporin, theophylline and digoxin have been reported during propafenone therapy. Doses of these medicinal products should be reduced, as appropriate, if signs of overdose are observed.

SSRIs: Use with caution due to potentially elevated levels of plasma propafenone when concomitantly with SSRIs

Anticoagulants: Propafenone may enhance effects of anticoagulants e.g. warfarin, phenocoumarol. Close monitoring of the clotting status advised

CYP2D6, CYP1A2 and CYP 3A4 inhibitors e.g., ketoconazole, cimetidine, quinidine, erythromycin and grapefruit juice might lead to increased levels of propafenone. Prescribe with caution and monitor patients closely

Co-administration of ritonavir and propafenone hydrochloride is **contraindicated** due to the potential for increased plasma concentrations

Refer to SPC for full list of drug interactions

Cost: At current prices one year's treatment will cost £89.42 for 150 mg TDS dose (UK Drug Tariff December 2019)

References:

1. Propafenone SmPC – available at https://www.medicines.org.uk/emc/medicine/28909 Accessed 12/12/2019
2. December 2019 Electronic Drug Tariff. Department of Health. Available at http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx (accessed 12th December 2019)