SHARED CARE AGREEMENT

Name of medicine thioridazine

Indication for the treatment of schizophrenia in adults

Version: **1.0** Approval date: **April 2014** Review date: **April 2016**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Policy and Procedures for the Shared Care of Medicines, available at: http://intranet.lothian.scot.nhs.uk/NHSLothian/NHSLothian/BoardCommittees/AreaDrugTherapeutics/Pages/ADTCRelatedDocuments.aspx

Roles and Responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Initiation of therapy with thioridazine over a six week period and continue to supply until dose is stable.
- Patient monitoring at baseline, before each dose increase, one week after reaching maximum dose and at six monthly intervals once stable.
- Review the patient and prescribed treatment at least once a year.
- To ensure the patient is fully informed about their treatment.

General Practitioner

- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines.

Patient, Relatives, Carers

- As listed in the NHS Lothian Policy and Procedures for the Shared Care of Medicines.

Support and Advice for the GP

For individual queries
Contact the relevant Consultant Psychiatrist responsible for prescribing.

For general queries
Contact your local Mental Health Services

Key information on the medicine

Please note that due to unlicensed status of this product prescribing information is not available in the British National Formulary (BNF), or via a Summary of Product Characteristics (SPC)

Background to disease and use of drug for the given indication
Thioridazine had previously been used in the treatment of schizophrenia for many years however in December 2000 the Committee on Safety of Medicines (CSM) advised that the use of thioridazine be restricted. This was in response to accumulating data that thioridazine causes dose-related QTc interval prolongation that predisposes to potentially fatal Torsades de Pointes. In July 2005 the MHRA withdrew the UK license for thioridazine following the voluntary withdrawal of the branded Melleril® product from the world market.

Under the 'NHS Lothian Policy and Procedures for the Use of Unlicensed Medicines June 2014 http://intranet.lothian.scot.nhs.uk/NHSLothian/NHSLothian/BoardCommittees/AreaDrugTherapeutics/MedicinesGovernancePoliciesADTCPolicyStatements/Pages/default.aspx an application was made to continue thioridazine for selected patients who were unable to withdraw from it previously. It was classified as Amber under the policy and deemed suitable for continuation under shared care agreement.

Key information on the medicine (Continued)

Indication
Thioridazine is indicated for **second line treatment of schizophrenia** only. It should be reserved for continuation therapy in patients who have been unable to withdraw from thioridazine on previous attempts.

It may also be considered for recommencement in patients where this has been found to be a successful treatment in the past, and when no other LJF listed antipsychotic is effective or tolerated. However, prescribing of thioridazine for new patients will be by **specialists only**.

Dosage and Administration
150-300mg daily (initially in divided doses), maximum 600mg daily

Thioridazine is no longer licensed in the UK but can be imported on an unlicensed basis via IDIS World Medicines Ltd, Millbank House, 171-185 Ewell Road, Surbiton, Surrey KT6 6AX. Telephone 020 8410 0710

Monitoring
Monitoring should be undertaken by the specialist team

Test	Frequency	Abnormal result	Action if abnormal result
ECG	Baseline Before each dose increase After 1 week at maximum dose Every 6 months once stable	Do not initiate thioridazine if baseline QTc interval is >450msec (males) and >470msec (females)	Gradually discontinue thioridazine over 1-2 weeks if QTc interval greater than 500msec
Serum Ca^{2+}, Mg^{2+} and K^{+} levels	Baseline Before each dose increase Every 6 months once stable		Any imbalance of Serum Ca^{2+}, Mg^{2+} and K^{+} levels should be corrected if patient is to be initiated/ maintained on thioridazine

Cautions, contraindications
- Clinically significant cardiac disorders, including cardiac failure, angina, cardiomyopathy, LV dysfunction, QTc interval prolongation or family history of such, bradycardia, 2nd or 3rd degree heart block
- Uncorrected hypokalaemia or hypomagnesaemia
- Comatose states, dementia, and severe depression of the CNS
- A history of ventricular arrhythmias, Torsades de Pointes, hypersensitivity reactions (including photosensitivity), or serious haematological conditions
- Genetically reduced/ absent cytochrome P450 2D6 activity
- Hypersensitivity to any ingredient

Adverse effects
Drowsiness, sedation, anticholinergic side effects, orthostatic hypotension; also tardive dyskinesia, hyperprolactinaemia, blood dyscrasias, weight gain, oedema, neuroleptic malignant syndrome, photosensitivity, hepatic dysfunction.

Drug interactions
Avoid concurrent use of:
- drugs that prolong QTc interval e.g. amiodarone, sotalol, disopyramide, tricyclic antidepressants (TCAs), certain antihistamines, lithium
- inhibitors/substrates of cytochrome P450 2D6 e.g. anti-arrhythmics, SSRIs, TCAs, beta-blockers, opiates, MDMA

Be aware that interactions will not automatically flag up on electronic prescribing systems as thioridazine is an unlicensed product in the UK.

Choose alternative treatment or correct and monitor electrolyte balance with:
- drugs affecting electrolyte balance e.g. thiazide & loop diuretics, steroids, β2 agonists

Approved for use by the Hospital and Specialist Services Medicines Committee on 30 April 2014
and the General Practice Prescribing Committee on 17 June 2014