

SHARED CARE GUIDELINE

Title: Risperidone Long Acting Injection (risperidone LAI)/ Risperdal Consta	
Scope: Treatment of schizophrenia	Version: Version 2
Issue date:	
Replaces:	Version 1
Author(s)/Originator(s)	Pennine Care NHS Foundation Trust
To be read in conjunction with the following documents:	Risperdal Consta. Summary of Product Characteristics (SPC) Pennine Care NHS Foundation Trust. Shared Care Guideline for the prescribing and monitoring of second generation antipsychotics
Authorised by:	Drugs and Therapeutics Committee
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1. Introduction

Risperidone Long Acting Injection (risperidone LAI) is licensed for the maintenance treatment of schizophrenia in adults currently stabilised with oral antipsychotics. This shared care guideline covers its use in the primary care setting following its initiation in secondary care under the supervision of a Consultant Psychiatrist.

2. Scope

- Pennine Care NHS Foundation Trust
- NHS Bury
- NHS Heywood, Middleton and Rochdale
- NHS Oldham
- NHS Stockport
- NHS Tameside & Glossop

3. Clinical condition being treated

- The maintenance treatment of schizophrenia.

- Only patients initiated in secondary care and deemed to be on a stable maintenance dose of risperidone LAI should be managed under this Shared Care Guideline
- The patient should continue to be under the care of secondary care mental health services with respect to the Care Programme Approach or a Care Plan.

4. Product information and treatment regimen to be used

- Risperidone LAI is supplied as a single dose pack containing a vial of white powder (microspheres of risperidone) and a pre-filled syringe of clear solvent. Before use, the microspheres are suspended in the solvent according to the manufacturer's directions.
- Treatment is administered as a dose of 25mg, 37.5mg or 50mg every two weeks by deep intramuscular deltoid or gluteal injection using the appropriate safety needle and according to the manufacturer's directions. After initial injection, the main release of risperidone starts from week 3, is maintained from 4-6 weeks and subsides by week 7.
After repeated injections, the combination of the release profile and the fortnightly dosage regimen results in sustained therapeutic plasma concentrations.

5. Regimen Management

a) Aspects of care for which the Consultant Psychiatrist / specialist service is responsible

- Assessing the suitability of the patient for treatment. Refer to the Trust Guidelines and Requirements for the prescribing of risperidone LAI (MM059)
- Initiation of treatment.
- Discussion of benefits and side effects of treatment with the patient.
- To arrange for the following baseline tests to be carried out: LFT, FBC, U&E, weight, waist circumference, BMI, blood pressure, blood lipids, plasma glucose and prolactin.
- Titration of dose to establish the patient on an appropriate dose of risperidone LAI and to prescribe until the maintenance dose is established.
- To ask the General Practitioner (GP) whether they are willing to participate in shared care
- To advise the GP of any dosage adjustments required, when to refer back and when to stop treatment (if appropriate).
- Reporting of any adverse events to the Medicines and Healthcare Regulatory Agency (MHRA).
- Ensuring that arrangements are in place for the administration of the risperidone LAI.
- Ensuring there are clear arrangements for back-up advice and support.

b) Aspects of care for which General Practitioner is responsible

- Replying to the request for shared care as soon as practicable.
- To prescribe the risperidone LAI once patient is stabilised on treatment.

- To ensure there are no interactions with any other medication initiated in primary care
- Ensuring that arrangements are in place for the administration of the risperidone LAI.
- To continue monitoring as agreed with the specialist service.
3 months after initiation: Weight, waist circumference, BMI and blood lipids
6 months after initiation: Plasma glucose and prolactin
Annually: LFT, U&E, FBC, plasma glucose, weight, waist circumference, BMI and prolactin.
- Liaising with Community Psychiatric Nurse (CPN) or practice nurse administering the injection regarding the follow up of patients in the event of non-attendance.
- Referral back to the Consultant Psychiatrist/ specialist service if the patient's condition deteriorates.
- Assessing adverse effects and reporting of any adverse events to the Medicines and Healthcare Regulatory Agency (MHRA) via the Yellow Care scheme. Also informing the Consultant Psychiatrist.
- Ideally arrangements should be made between the GP and a specified local community pharmacy to ensure that the prescriptions for risperidone LAI can be completed in a timely fashion.

c) Aspect of care for which CPN / Practice Nurse is responsible

- Ensuring that arrangements for the collection and storage of the risperidone LAI maintain cold chain requirements.
- Administering risperidone LAI.
- Recording administration on the Trust 'Long acting IM antipsychotic injection prescription and administration record card' (depot card) and/ or other shared care document.
- Assessing adverse effects.
- Informing GP and Consultant Psychiatrist/ specialist service of any difficulties such as non-adherence and adverse effects .
- Reporting adverse events to the Medicines and Healthcare Regulatory Agency (MHRA) via the Yellow Card scheme

d) Monitoring requirements

For all further monitoring required, please refer to the Pennine Care NHS Foundation Trust Shared Care Guideline for the prescribing and monitoring of second generation antipsychotics.

6. Summary of cautions, contra indications, side-effects

- Risperidone LAI is contraindicated in patients with a known hypersensitivity to the product or the diluent.
- The most frequently reported adverse effects are insomnia, anxiety, headache, upper respiratory infection, parkinsonism, depression and akathisia. Refer to the full Summary of Product Characteristics (SPC) for full list of side effects.

- Risperidone LAI should be used with caution in combination with alcohol, opiates, benzodiazepines, and medicinal products known to prolong the QT interval.
- Risperidone LAI should not be used in pregnancy and/or lactation unless clearly necessary.
- Patients should be advised not to drive or operate machinery until their susceptibility to nervous system and /or visual side effects is known.

7. Special considerations

- Staff administering risperidone LAI should be familiar with the device and have received training in its use.
- Risperidone LAI should be stored at 2-8°C. Once the preparation has left strict cold-chain control, it must be used within 7 days.
- If refrigeration is unavailable, risperidone LAI can be stored at temperatures not exceeding 25°C for no more than 7 days.
- After reconstitution the injection should be used immediately.

8. Back-up care available to GP from Hospital, including emergency contact procedures and help line numbers

- The on-call psychiatry service can be contacted via the switchboard of the local hospital. When the concern is related to a specific patient and is in office hours then the GP and Consultant Psychiatrist should attempt to contact each other in their respective places of work.
- Full Community Mental Health Team (CMHT) contact details are available in the Pennine Care NHS Trust Shared Care Protocol for the Prescribing and Monitoring of Atypical Antipsychotics.

9. Statement of agreement

This form is a request by the Consultant/ specialist service to share the suggested care pathway of the patient. If a GP is unable to agree to the sharing of care and prescribing this should be made known to the Consultant/ specialist service within 14 days, stating the nature of the concern.

10. Written information provided to the patient

Patient Information Leaflet

11. Supporting References

Risperdal Consta, Summary of Product Characteristics.
www.Medicines.org.uk accessed on 15/9/2009