NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Shared care guidelines – Risperidone LAI

Drug	**RISPERIDONE** long-acting injection (Risperdal Consta®)
Specialty	ALL SPECIALTIES (excluding Children & Young People's Services)
Indication	SCHIZOPHRENIA
Overview	Risperidone binds strongly to serotonergic 5-HT_2 & dopaminergic D_2-receptors; also blocking alpha$_1$-adrenergic receptors & slightly less, H_1-histaminergic & alpha$_2$-adrenergic receptors. Risperidone long-acting injection is administered 2-weekly (Risperdal Consta®). It should be initiated by a specialist with expertise in schizophrenia as part of a comprehensive treatment plan but prescribing, administration & monitoring responsibility can transfer to GPs under these shared care guidelines.
Specialist responsibilities	**Pre-treatment:** *(see SPC for Risperdal Consta for full details of contra-indications & cautions)* Assess suitability for treatment with risperidone long-acting injection by reviewing the patient's medical history, completing a physical examination, and completing the baseline monitoring as detailed in appendix 1; dose adjustment is necessary in renal impairment. Risperdal Consta® is indicated for the maintenance treatment of schizophrenia in patients who are already stabilised on oral antipsychotics. **Initial prescription - dosage and administration:** *(see BNF, SPC and North of England Guidance for prescribing LAI for full details)* For patients taking 4 mg or less of oral risperidone per day, a dose of 25 mg Risperdal Consta® every two weeks is recommended. A higher starting dose of 37.5 mg Risperdal Consta® every two weeks is recommended for patients taking more than 4 mg of oral risperidone per day. For patients taking other oral antipsychotics, the recommended starting dose of Risperdal Consta is 25 mg every two weeks. For patients on higher doses of the oral antipsychotic, a higher dose of 37.5 mg every two weeks should be considered. Sufficient oral antipsychotic cover should be provided during the initiation phase either with oral risperidone or the previous antipsychotic due to the three-week lag period following the first injection. **Maintenance** The recommended maintenance dose is 25 mg every two weeks, although some patients may benefit from higher doses of 37.5 mg or 50 mg every two weeks. Dose adjustments should not be made more frequently than every four weeks; the effects of the dose adjustment should only be anticipated three weeks after the dose adjustment. Doses higher than 50 mg every two weeks are not licensed or recommended and have not shown any additional benefit in clinical trials. **Monitoring** – see appendix 1: The baseline efficacy and tolerability of antipsychotic medication should be established using objective and validated measures. • **Side effects** – use LUNSERS or GASS to assess tolerability at each review • **Physical Health monitoring** – for the first 12 months of treatment, then at each review (at least annually); see physical parameters in appendix 1 • **Clinical response** – use appropriate measures, e.g., PANSS (positive and negative syndrome scale), CGI (clinical global impressions) and GAF (global assessment of functioning), to assess response prior to transfer and at each review. Where tolerability or clinical response is not demonstrated, the LAI should not continue to be prescribed. The on-going clinical need and patient preference for a LAI should be reviewed at least annually.

Specialist responsibilities *(continued)*

Transfer of prescribing / communication
Prescribing, administration and monitoring responsibility may be transferred to the patient's GP after 3 months or once the treatment has been stabilised, whichever is the longer. The request must be made using the attached form with a covering clinic letter and a copy of this guideline (with contact details added) – the following details should be clearly communicated at transfer, and after each subsequent review:

- **Diagnosis**
- **Dose** of risperidone and **formulation**
- **Date** and **site** of last administration, and **date when next dose is due**
- Completed and required **monitoring**
- **Discontinued medication** for same diagnosis
- **Date** of next specialist review

The transfer request should be sent one month in advance of the patient needing their next dose. Acceptance should not be assumed until the GP responds positively using the attached form (scanned & e-mailed to the specialist team).

GP responsibilities

Transfer of prescribing / communication:
Notify specialist immediately (within 2 weeks) if transfer of prescribing & monitoring responsibility is not accepted so that alternative arrangements can be put in place. Contact specialist if communication of prescribing, administration & monitoring requirements is not clear.

Maintenance (repeat) prescription:
Prescribe risperidone LAI (by brand name) in accordance with specialist advice received on transfer and following reviews

Risperdal Consta® recommended maintenance dose is 25 mg every two weeks; some patients may benefit from higher doses of 37.5 mg to 50 mg every two weeks based on individual patient tolerability and/or efficacy.

Administration:
Risperidone LAI can be administered into either the deltoid or gluteal muscle. See relevant *SPC* and appendix 2 for detailed information regarding administration and action to take in response to missed or delayed doses.

Monitoring – see appendix 1:
Efficacy and tolerability measures should be completed by the specialist team prior to transfer and at each review. Physical health monitoring should be completed by the specialist team for the first 12 months, then at each review (at least annually); any additional physical health monitoring by GP should be communicated to the specialist.

Referral:
Seek advice or refer back to the specialist should any of the following occur:

- Significant adverse reaction or intolerable side effects
- Lack of efficacy/ patient's condition deteriorates
- Development of co-morbidities
- Pregnancy
- Failure to attend for administration of risperidone within the permitted timeframe (+/- 1 day)

Adverse events

See BNF and SPC for full details of known adverse effects.
Short-term side effects include insomnia and headache. These effects should not persist. Risperidone can raise the levels of plasma glucose, lipids and prolactin. Weight gain is common. Akathisia and extrapyramidal side effects may occur at higher doses. Risperidone has a low effect on the cardiac QTc interval (average change <10 msecs). Report any suspected adverse events to MHRA via the Yellow Card scheme

Specialist contact details
(to be added by specialist prescriber when transferring prescribing)

Name:
Base:
Telephone no:
E-mail address:

AMBER ▲	TRANSFERRING PRESCRIBING & ADMINISTRATION OF LONG ACTING / DEPOT INJECTIONS

GP details:

Patient details (name/address/DOB/NHS number):

Diagnosis:

Medication details:

The patient is stabilised on: (list dose, frequency and brand. Specify clinical indications if first line option not prescribed or non-standard formulation prescribed):

Discontinued medication (list details of any drugs discontinued when this AMBER treatment initiated):

Last Administration (details of date and site of administration and date next dose due):

Monitoring results:

Secondary care review frequency:

Actions requested of GP:

Please continue to issue prescriptions and administer fortnightly Risperdal Consta® until advised otherwise

The treatment has been explained to the patient and they understand they should contact you for future prescriptions.

You will be informed of any changes to treatment, if you are not required to issue prescriptions or if treatment is to be discontinued.

Please contact the prescriber on the number below if there is any change in the patient's condition, if the patient fails to regularly collect prescriptions, if non-compliance with treatment is suspected or you require advice.

Secondary care contacts:	Contact details (address/telephone no):
Care coordinator (name):	
Consultant (name):	
Prescriber (name):	
Signature & date:	

Acceptance of prescribing responsibility by GP (scan & e-mail)

Patient's name:	NHS Number:
Address:	
Medication:	
I confirm receipt of prescribing transfer information for the above patient and accept prescribing responsibility	
GP's name: *(Please print name in BLOCK CAPITALS*)	
Signature/ Practice Stamp:	
Date:	

Please scan and email back to:
Email address:
or return as soon as possible to:

Appendix 1 Monitoring requirements for antipsychotic long-acting injections (from *PHARM-0082 Psychotropic Medication Monitoring Guide*)

Test/ Measurement	Why is it important?	Baseline	3 months after initiation	Annually
Weight (Waist measurement and BMI where possible)	Antipsychotic drugs can cause weight gain and this can contribute to an ↑ risk of cardiovascular and metabolic problems	✓ Then weekly for the first 6 weeks	✓	✓
Lipids (Total cholesterol, HDL cholesterol, Total/HDL-cholesterol ratio, Triglycerides - fasting sample if possible)	Some antipsychotics can cause small adverse changes in lipid profiles. Triglyceride levels can rise during periods of weight gain.	✓	✓	✓
Blood Glucose - HbA_{1c}	Antipsychotics can increase the risk of developing diabetes.	✓	✓	✓
Blood Pressure (sitting / lying and standing) **and pulse**	Hypotension is a side effect of many antipscyhotics and it is important to monitor this during peiods of initation and stabilisation. Longer term it is important to montior and manage factors that inluence a patients CV risk	✓	Frequently during dose titration (determined by clinical situation) and also after 12 weeks	✓
Prolactin *(see PHARM-0032 Hyperprolactinaemia)*	Antipsychotics can increase prolactin levels. This can inhibit sex hormones – oestrogen and testosterone and may ↑ risk of osteoporosis	✓		
ECG (QTc Interval)	Many antipsychotics are associated with ECG changes and some are linked to prolongation of the QT interval. All new inpatients should have an ECG on admission. For long stay patients and those in the community - ECGs should be performed at baseline and annually when clinically indicated. Factors that may determine if ECG is clinically indicated include: • personal history of cardiovascular disease (e.g. known ischaemic / structural heart disease QT prolongation), • physical examination identifies cardiovascular risk factors • antipsychotic that requires ECG monitoring i.e. haloperidol or pimozide (check summary of product characteristics for more information) • high dose antipsychotic therapy (HDAT) • concurrent drugs known to cause ECG abnormalities (e.g. tricyclic antidepressants, erythromycin, anti-arrhythmics – see BNF for further information) ○ factors which may predispose to arrhythmias including electrolyte abnormalities (hypokalaemia, hypocalcaemia, hypomagnesaemia) and systemic disease (liver disease, renal disease, hypothyroidism)	✓ (if clinically indicated)		✓ (if clinically indicated)
Review of the side effects of drug treatment, efficacy and adherence	Before treatment the side effects the patient is least willing to tolerate should be assessed. On review the treatment efficacy, patient adherence and side effects experienced should be assessed, including : • Extrapyramidal symptoms, akathisia, dystonia and tardive dyskinesia • Sexual side-effects • Less common but serious adverse effects e.g. palpitations. An appropriate rating scale may be useful (e.g. GASS, LUNSERS)	✓	✓	✓

Other tests to consider (not required for the drug itself)				
Test/ Measurement	**Why is it important?**	**Baseline**	**3 months after initiation**	**Annually**
Urea and electrolytes (including creatinine or estimated GFR)	Pateints with renal impairment may have reduced capacity to excrete drugs and dose reductions may be required. Hypolkaleamia is linked to QTc prolongation and other ECG abnormaliites	✓		✓
Liver function (Bilirubin, Alk Phos, ALT, Albumin, Total protein, Gamma-GT)	Patients with hepatic impairment may have reduced capacity to metabolise drugs and dose reductions may be required. Drug induced liver damage can be due to direct dose related hepatotoxicity or hypersensitivity reactions. Risk factors for drug induced hepatotoxicity include - ↑age, female gender, alcohol, prescribed enzyme inducing drugs, obesity	✓		✓
Full Blood Count (Hb, WBC, Platelets)	BNF advises caution when using antipsychotics in patients with blood dyscrasias Antipsychotics can cause blood dyscrasias including agranulocytosis and leucopenia	✓		✓
Pregnancy test		If there is any uncertainty about the possibility of pregnancy, a urine pregnancy test should be carried out		
Smoking status	Linked to CV risk. Changes in smoking status may impact on drug metabolism, notably olanzapine and clozapine	✓	At each dose administration and each review	
Drug screening		If indicated by history or clinical picture		

Appendix 2 – Administration Information

Administration

Risperdal Consta® (See SPC for further details)

- Available in pre-filled syringes of 25mg, 37.5mg and 50mg.
- Should be stored in the fridge, between 2 and 8°C.
- If refrigeration is unavailable, Risperdal Consta® can be stored at temperatures not exceeding 25°C for no more than 7 days before administration.
- The injection should be reconstituted as per instructions in the SPC and used as soon as possible to avoid settling. The entire contents of the vial must be administered to ensure the full intended dose is delivered.
- The injection should be administered slowly as a single injection into either the gluteal or the deltoid muscle. The injection sites should be rotated between the two gluteal or deltoid muscles. Care should be taken to avoid inadvertent injection into a blood vessel.

Deltoid muscle administration, the recommended needle size is:
    - The 1-inch, 21 gauge safety needle (25mm x 0.8mm) as supplied in the pack
- Deltoid injections should be alternated between the two deltoid muscles.

Gluteal muscle administration, the recommended needle size is:
    - The 2-inch, 22 gauge needle (50 mm x 0.9 mm) as supplied in the pack.
- Administration should be made into the upper-outer quadrant of the gluteal area.
- Gluteal injections should be alternated between the two gluteal muscles.

Missed doses

Risperdal Consta® (See SPC for further details)

- Initiation doses will be administered by the specialist service, as per SPC.
- After initiation, the recommended injection cycle is once every 2 weeks
- To avoid a missed fortnightly dose, patients may be given the injection up to a day before or after the depot is due; the delayed release from Consta means a dose can be given as soon as possible after the missed dose and carried on every 2 weeks from this point.
- If a patient misses one fortnightly dose of Risperdal Consta®, the specialist team should be contacted for advice.