Bournemouth, Dorset and Poole Prescribing Forum

SHARED CARE GUIDELINE FOR PRESCRIBING RISPERIDONE IN CHILDHOOD NON-PSYCHOTIC DISORDERS

INDICATION

Within the "traffic light" system Risperidone has been classified as amber. This Shared Care Guidance has been prepared to support the transfer of prescribing of Risperidone from secondary to primary care within a shared care arrangement and is intended to apply to children over the age of 5years, who have been initiated and stabilised on Risperidone by a Consultant Paediatrician, with experience in neurodevelopmental disorders, or Consultant in Child and Adolescent Psychiatry as part of a comprehensive treatment programme.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested responsibilities for managing the prescribing of Risperidone in childhood non-psychotic disorders.

The indications for use are:-

- Severe aggression against self or others in ASD or learning difficulty where extreme over-arousal and anxiety seem to be part of the problem.
- Severe social dysfunction in children with ASD.
- Adolescents with a high level of arousal, anxiety or aggression when the family or school is on the verge of breakdown and where it can enable further therapeutic work to be undertaken. This means that these guidelines can apply to children with ADHD. However, Risperidone should not be considered to be a primary treatment of ADHD.
- Tourette's Syndrome.

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.

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

	Specialist Responsibilities
1	To provide specialist assessment and determine a management strategy
2	Where appropriate * to initiate and stabilise treatment * obtain consent and agreement from the patient's GP to continue prescribing once treatment has been stabilised; * monitor the patient and their therapy as clinically appropriate.
3	To ensure that the decision to go ahead with treatment is based on an informed discussion of the relative benefits of risperidone and its side effects with the patient and his/her parent guardian.
4	To provide the GP with appropriate prescribing information, reasons for the prescription of Risperidone, specific guidance on the monitoring required, on going management plans and results of any appropriate baseline monitoring.
5	To be available for advice if the patient's condition changes and accept referrals if necessary.
6	To ensure the patient (and/or his or her parent or guardian) has given informed consent to their treatment.
7	To obtain agreement from the patient's GP for the transfer of prescribing or management responsibility.
8	To provide the patient's therapy and sufficient prescriptions until such time as is practical for the GP to take over prescribing and supply.
9	To notify the GP of any changes in prescribed therapy or clinical status and ensure that the patient has sufficient medication until the GP has received this notification.
10	To review the patient at least every 6 months.

General Practitioner Responsibilities	
1	To initially refer the patient for specialist advice.
2	To reply to the request for shared care as soon as practicable.
3	To prescribe in accordance with directions agreed with the CAMHS specialist or Paediatrician.
4	To review and manage the patient in accordance with the management plan for the patient.
5	To seek specialist advice from the Child Psychiatrist or Paediatrician at such a time as is necessary.
6	To deal with general health issues of the patient and provide routine physical health checks – monitor increased risk of significant weight gain and diabetes and promote healthy lifestyle. Be aware of neurological, cardiac, metabolic and endocrine side effects including hyperlipidaemia, hyperglycaemia and weight gain. Monitor in line with specialist recommendation.
7	Monitoring concordance with therapy in partnership with the Child Psychiatrist or Paediatrican. Particular care should be taken in establishing arrangements for obtaining repeat prescriptions.
8	To notify the specialist of any relevant changes in other medications or clinical status or to refer the patient back to the specialist.
9	Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
10	**Indications for specialist advice include:-** o Any spontaneous deterioration in behaviour/mental state that cannot be managed by the GP; o Patient intolerance and/or adverse effects; o When considering the initiation of therapy that may interact with the patient's psychotropic therapy or mental state; o Non-concordance, lack of efficacy or need for alteration of dose of psychotropic therapy.

Patient's role (or that of carer)	
1	To take the medication regularly and enter a concordant relationship with those involved in the delivery of their care.
2	Report any adverse effects to their GP/specialist service nurse whilst taking the medication.
3	To ensure they have a clear understanding of their treatment.
4	Attend appropriate GP, Consultant and/or other follow up appointments
5	Share any concerns in relation to treatment with their GP or Consultant.
6	Use written and other information on the medication.
7	Seek help urgently if suspect side effects, or otherwise unwell.

SUPPORTING INFORMATION

It should be noted that a far as possible, medicines should be prescribed within the terms of the marketing authorisation. However, many children require medicines not specifically licensed for paediatric use. Although medicines cannot be promoted outside the limits of the license, the Medicines Act does not prohibit the use of unlicensed medicines. Risperidone is not licensed for those under 15 years of age. However, the enclosed advice reflects careful consideration of the current evidence and experience of this atypical antipsychotic in children. Limitations of the marketing authorisation should not preclude unlicensed use where clinically appropriate. Further information of risperidone use in children is available in the most recent Edition of the BNF for Children (www.bnfc.org).

Antipsychotic medication is used for patients with psychotic illness. Their use is not licensed for use in patients under the age of 15 years or for the treatment of disruptive behaviour disorders. However there is increasing evidence regarding the use of Risperidone for Autistic Spectrum Disorders (ASD), Attention Deficit Disorder (ADHD) and Tourette's syndrome. Further information and support documentation is available in the West Dorset Mental Health Drug and Therapeutics Committee's Guideline for the Use of Risperidone in Childhood Non-psychotic Disorders.

Special consideration needs to be given to prescribing Risperidone in children and adolescents who may have significant side effects which are yet unrecognised. They will also have greater difficulties communicating their

concerns because of developmental issues. Risperidone should be used with caution, commenced at low doses and increased gradually.

Children should be involved in decisions about taking medicines and encouraged to take responsibility for using them correctly. The degree of such involvement will depend on the child's age, understanding, and personal circumstances.

DOSE

Dosage requirements vary

- Initial daily dose of 0.25mg/ 0.5mg
- Dosage titrated against clinical need up to a dose of 3mg daily (In exceptional circumstances, to be documented, higher doses may be used)
- It can be considered for ASD from 5 years upwards.
- For ADHD it would be unusual for Risperidone to be prescribed below the age of 10 years.

When prescribing has been initiated by a specialist and the patient established on an appropriate dose, transfer to primary care can be considered according to the following criteria:

- The patient's behaviour/mental state has been stabilised
- The patient's GP has agreed to take on prescribing responsibility of the patient under shared care.
- A review date has been documented.
- Appropriate information has been received by the patient's GP via letter, fax or telephone call, including details of previous therapy and a copy of the care plan;
- The GP is aware of their role in the patient's care plan, has agreed to be involved in the patient's care.

FORMULATIONS

Risperidone tablets (Risperdal^{R}) are available as 0.5mg, 1mg, 2mg, 3mg, 4mg or 6 mg. Risperidone can be given as a single dose or the daily dose split 12hourly.

Risperidone liquid 1mg per ml (Risperdal Liquid^{R}).

Risperidone Orodispersible tablets tablets (Risperdal Quicklets^{R} – Formulary for use in children and adolescents only) contain risperidone 0.5mg, 1mg or 2 mg. When placed on the tongue the quicklet disintegrates. It can be swallowed with or without water. Quicklets should not be cut or divided in any way and care should be taken when removing them from their packaging as they are fragile. Taking a split or broken tablet could result in a sub-therapeutic dose.

Risperidone orodispensible, oral solution and oral tablets are bio-equivalent. Peak plasma concentration occurs in 1 to 2 hours. The active antipsychotic fraction has a half life of 24 hours.

SIDE-EFFECTS

- Weight gain, very common but especially true for those with low IQ
- Fatigue
- Insomnia
- Agitation
- Anxiety
- Headache
- Type I and II diabetes and lipid changes
- Blood dyscrasias
- Cardiac arrythmias
- Prolonged QT interval if given with other drugs with this effect
- Elevated prolactin
- Seizures
- Dystonias
- Neuroleptic malignant syndrome
- Acute withdrawal syndrome – gradual withdrawal is advisable

Refer to Summary of Product Characteristics or http://emc.medicines.org.uk for further product specific information or current edition of BNF/CBNF.

Written By	**Mental Health Sub-Group**	**April 2008**
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Review Date	**April 2010 or before in the light of new evidence and/or recommendations**