

## Shared Care Protocol for the use of Methylphenidate (Ritalin®, Equasym®, Equasym XL, Concerta XL® Medikinet, Medikinet XL) in Attention Deficit Hyperactivity Disorder in Childhood

Surrey PCT's Medicines Management Committee classification: *Amber\**

*Amber\**: Drugs that require initiation by a specialist in secondary/tertiary care but due to more widespread experience in primary care GPs are generally happy to prescribe on specialist advice without the need for a formal shared care protocol. This information sheet is available on the internet ([www.surreyhealth.nhs.uk](http://www.surreyhealth.nhs.uk)) forming part of Surrey's PCT's traffic light document giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter. A minimum of one month supply of medication will be provided by the initiating consultant.

### Criteria for Use

- The diagnosis of ADHD is made by a Child Psychiatrist or a Specialist Paediatrician after a comprehensive assessment which includes the completion of Conner's questionnaires by the carers and teachers. If there is significant co-morbidity such as learning difficulties or other mental health problems, a full multidisciplinary assessment is advised. If medication is indicated as part of the treatment package, an initial prescription for Methylphenidate is given by the Consultant for a trial period of one month.
- If improvement of symptoms is not observed after appropriate dosage adjustment over the one month period, the drug should be discontinued by the Consultant. The medication may be stopped abruptly; there is no tailing off necessary.
- The drug may be discontinued periodically to assess the child's condition as advised by the Consultant.
- It is the Consultant's responsibility for stopping methylphenidate or to agree aftercare when the patient reaches 18 years of age.
- All children and families with a child taking methylphenidate should receive psychological and / or educational interventions with a view to improving the symptoms of ADHD and allowing children to reduce their need for medication. The extent of these interventions and the level of need will be assessed and agreed with the individual clinician and family.
- Explanations given to the family about medication are important. For example children should not be told that the medication is the only thing that can control their behaviour. Explanations should always seek to foster healthy development trajectories for children.
- Prescriptions should be written in accordance with the Misuse of Drugs Act
- Some clinicians use methylphenidate on school days only where the effect sought may relate mainly to education and this is recognised practice.

### Responsibilities of the Consultant

- Diagnosis of ADHD and decision to initiate treatment.
- Ensure baseline monitoring of height, weight, BP have been performed plus any additional relevant investigations such as ECG in case of family history of arrhythmia or sudden death.
- Initiation and stabilisation of drug treatment. The GP is not expected to enter into a shared care agreement until the patient is stabilised on methylphenidate and the parents at this stage are instructed to communicate directly with the clinic. This usually takes one month.
- Liaison with other members of the multidisciplinary team responsible for the child's development. The parents and class teachers are given information about methylphenidate in particular monitoring the effects and side effects of treatment, including the potential effects on blood cells. To assess the effects of the medication continued liaison is required with the parents and class teachers.
- To supply the medication until the dose is stabilised.
- Set the review interval and criteria. Follow up should take place in the Consultant led clinic four weeks after initiation of the treatment to assess if it is being effective. Further follow up should then take place in the Consultant led clinic within four months alongside school liaison. Once a child's treatment is stabilised, six monthly review appointments are offered by the Consultant. Specialist ADHD nurse, junior doctors and other staff are closely involved with the monitoring of the patients. When junior / middle grade doctors are helping the Consultants in the clinic, changes should be made after discussion with the Consultant only, and should be clearly stated in a letter to the GP.
- Undertake any necessary monitoring at clinic appointments: blood pressure, pulse rate, weight and height (including centiles). Unless the child has symptoms routine monitoring of full and differential blood counts are not carried out.
- Arrange shared care with the GP once stabilised on medication. The GP will not be asked to prescribe the drug outside its licensed indications.
- Stop or modify the dosage as appropriate.
- Maintain good communication with the GP. A written letter should be sent to the GP after each clinic visit notifying the GP of changes in medication regime, adverse effects and results of the patient's routine monitoring. A copy of all correspondence / advice should be sent to Goldsworth Park health Centre or Ashford

- Clinic (which ever is appropriate) and to the school doctor for the named school to ensure all are aware of the treatment plan and doses.
- This information could be shared with the teachers in the relevant school if the carers give consent for this to happen. Ideally the school doctor will monitor the child's clinical condition within school and act as a supporter and local advisor.
  - Provide contact information should further assistance be needed.
  - Be available to discuss any problems with the GP and other team members
  - Evaluate adverse drug reactions reported by the GP, school doctor or carer.
  - Explain to the patient / carer their roles.

## Responsibilities of the GP

- Some GP's may feel able to make diagnosis of ADHD. Psychoeducation and parent training can take place in primary care for children who have mild or moderate ADHD.
- Other GP's will initiate referral to secondary care on suspicion of ADHD to refer children who are severely affected by ADHD should be referred to secondary care without delay. These children will require medication early as part of the treatment package.
- GP should monitor patient's overall health and well being.
- GP should continue prescription of treatment, once patient is stabilised on medication and shared care is agreed, at the appropriate intervals given the nature of the drug and the family involved (usually 3 monthly). It is not necessary for a doctor to see the child more than every 3-6 months, unless there are specific indications. Repeat prescriptions can be issued without necessarily seeing the child on each occasion.
- GP should check that the patient is attending their six monthly specialist ADHD clinics and thus continued prescription is required.
- GP should manage minor adverse effects if patients are symptomatic.
- GP should report any adverse effects to the consultant and CSM where appropriate.
- GP should refer back to consultant if any problems arise.

## Patient's / Carer's roles

- Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with Methylphenidate.
- Tell the specialist or GP of any other medication being taken, including over-the-counter products.
- Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP.

## Back-up Advice and Support

Contact details	Specialist	Telephone No:	E-mail address:
Specialist:	Dr B Zoritch	01932 722126	bozhena.zoritch@asph.nhs.uk
Hospital Pharmacy:	Debbie Hopper	01932 723359	deborah.hopper@asph.nhs.uk

Shared Care Protocol for the use of Methylphenidate (Ritalin®, Equasym®, Equasym XL, Concerta XL®, Medikinet, Medikinet XL) in Attention Deficit Hyperactivity Disorder in Childhood

**Section 2 : Information**

This guideline follows the recommendations of NICE guidance (no 13) on the use of methylphenidate (Ritalin, Equasym, Medikinet, Concerta) for Attention Deficit / Hyperactivity disorder (ADHD) in childhood<sup>1,9</sup>.

**Dose / Licensing**

- Methylphenidate is indicated for use as part of a comprehensive treatment programme, where remedial behavioural methods alone have failed. Various trials show that the most effective treatments are those combining treatments with medication, but the resource implications of this means that many children would receive no care and medication alone does show significant gains<sup>1</sup>. A Canadian meta-analysis<sup>2</sup> and another trial<sup>3</sup> show that drug therapy alone is as efficacious as combined drug/ psychosocial therapy, but that either may not improve academic performance.
- A study<sup>4</sup> looking at stimulant treatment over five years indicates that children with ADHD continue to derive benefit and continue to experience adverse effects from ongoing use of stimulants. They conclude that for children with significant symptoms, using stimulants consistently over several years remains therapeutic with ongoing clinical monitoring required to maximise benefit and to limit adverse effects.
- Methylphenidate is not licensed for children under 6, but may be so used under certain circumstances by the consultant. It is usually discontinued during adolescence.
- Methylphenidate is a controlled drug subject to safe custody and handwriting regulations on prescriptions where total quantity to be supplied must be specified in both words and figures.
- Dose initially starts at 5mg once or twice daily (morning and lunch time) and is then gradually titrated up to a maximum of 60mg daily in divided doses at intervals of 3-4 hours. The dose should be titrated up by weekly increments of 5-10mg of the total daily dose.
- The patient can be changed to the m/r preparation if appropriate up to a maximum of 54mg once daily (see Concerta XL SPC for details<sup>5</sup>)
- Twice daily doses are usually given in the morning and at lunchtime, however if the effect of the drug wears off to early in the evening disturbed behaviour and or inability to sleep may recur. A small evening dose may help to solve this problem.
- If improvement of symptoms is not observed after appropriate dosage adjustment over a one month period the drug should be discontinued by the consultant.

**Cost**

Drug	Dose	Cost
Ritalin	Initially 5mg once or twice daily gradually titrated to a maximum of 60mg daily in divided doses.	30 x 10mg tablets: £5.20 Max recommended dose: 60mg daily (£31.20 / month)
Equasym	Initially 5mg once or twice daily gradually titrated to a maximum of 60mg daily in divided doses.	30 x 5mg tablets: £3.04 30 x 10mg tablets : £5.47 30 x 20mg tablets : £10.95 Max recommended dose: 60mg daily (£32.85 / month)
Equasym XL	Initially 10mg once daily gradually titrated to a maximum dose of 60mg daily in divided doses.	30 x 10mg capsules: £25.00 30 x 20mg capsules: £30.00 30 x 30mg capsules: £35.00
Medikinet XL	Initially 10mg once daily gradually titrated to a maximum dose of 60mg daily in divided doses.	28 x 10mg capsules: £21.00 28 x 20mg capsules: £28.00 28 x 30mg capsules: £33.72 28 x 40mg capsules: £44.95
Concerta XL	Initially 18mg once daily gradually titrated to a maximum of 54mg once daily N.B. Janssen-Cilag have recently applied for a license extension up to a maximum dose of 72mg once daily and are hoping to hear in the near future whether they have been successful.	30 x 18mg tablets: £25.20 30 x 36mg tablets: £34.30 Max recommended dose: 54mg daily (£59.50 / month)

- Estimated total cost of first year treatment (drugs only) £678, cost per QALY £7,500-9,000 approx<sup>6</sup>

## Cautions

- Must only be used under the supervision of a specialist in childhood behavioural disorders.
- Moderately reduced weight gain and slight growth retardation have been reported with the long-term use of methylphenidate: monitor height and weight.
- Hypertension, monitor blood pressure.
- Epilepsy, increase seizure frequency observed in a small number of patients, discontinue if seizure frequency increases. Incidence of ADHD is however increased in children with epilepsy.
- Pregnancy, lactation.
- Careful supervision is required during drug withdrawal since this may unmask depression as well as chronic over-activity.
- Concerta XL must be swallowed whole with the aid of liquids and must not be chewed, divided or crushed.
- Motor tics, tics in siblings or a family history or diagnosis of Tourette's syndrome.

## Contra-indications

- Children with marked anxiety, agitation or tension.
- Hyperthyroidism, severe angina pectoris, cardiac arrhythmias, glaucoma, thyrotoxicosis.
- Known sensitivity to methylphenidate.
- Use in care where there is a history of drug or alcohol abuse. Alcohol should be avoided.

## Interactions

- Methylphenidate may inhibit the metabolism of coumarin anticoagulants, some anticonvulsants (phenobarbitons, phenytoin and primidone), phenylbutazone and tricyclic antidepressants. The dosage of these drugs may have to be reduced
- Use in caution with MAOI
- Alcohol may exacerbate the adverse CNS effect of methylphenidate. Patients should be advised to abstain from alcohol during treatment.
- Pseudoephedrine, phenylpropanolamine (both found in OTC cough remedies). Patients should be warned when buying cough medicines.

## Side effects<sup>5,7,8</sup>

Frequency	Side effect
Very Common: >10%	<ul style="list-style-type: none"> <li>• Nervousness and insomnia at onset of treatment – reduce the dosage and / or omit the afternoon or evening dose. (If severe can be helped by adding Clonidine but additional monitoring required with ECGs etc, initiated by consultant only)</li> </ul>
Common: >1% to <10%	<ul style="list-style-type: none"> <li>• Decreased appetite – transient, give bedtime snack which helps sleep as the effect of afternoon dose should be wearing off.</li> <li>• Headache, drowsiness, dizziness and dyskinesia – paracetamol helps</li> <li>• Abdominal pain, nausea and vomiting. Usually occur at beginning of treatment and often eased by taking with food</li> <li>• Dry mouth</li> <li>• Tachycardia, palpitations, arrhythmias, changes in blood pressure (usually upwards)</li> <li>• Rash, pruritis, urticaria, fever, arthralgia and hair loss</li> </ul>
Rare: <1%	<ul style="list-style-type: none"> <li>• Blurred vision and difficulties in visual accommodation</li> <li>• Angina pectoris</li> <li>• Reduced weight gain and slight growth retardation with prolonged use</li> </ul>
Very Rare: <0.01%	<ul style="list-style-type: none"> <li>• Hyperactivity, convulsion, muscle cramps, tics etc see drug SPC</li> <li>• Abnormal liver function ranging from raised transaminase to hepatic coma</li> <li>• Thrombocytopenic purpura, exfoliative dermatitis and erthema multiforme</li> <li>• Leucopenia, thrombocytopenia and anaemia</li> </ul>

## Background

**Definition:** Attention Deficit Hyperactivity Disorder (ADHD) is one of the most commonly diagnosed behavioural disorders of childhood, affecting 1-5% of school age children. Its basic symptoms include developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity. It causes problems at home, in school and with peer relationships and may have long term adverse effects on self-confidence, academic performance, vocational success and social development.

- It can be divided into three types, depending in whether inattention or hyperactivity is the predominant presentation
- It must have been present for at least 6 months and be maladaptive and inconsistent for the age of the child.
- There must be clear evidence of impairment in social and / or academic functioning
- Some impairment must be present in at least two settings
- The symptoms must be present in at least two settings
- The symptoms must be present before the age of seven
- The symptoms must not be accountable for by any other type of mental disorder although they may occur in conjunction with some development disorders.

Its consequences are low self-esteem, emotional and social problems which may lead to further problems with drug abuse etc. in the longer term. These children's academic achievements are often very low consequently often leading to employment problems.

## Diagnosis

Should be made by a child / adolescent psychiatrist or paediatrician with a special interest in ADHD, involving the child, its carers, school and cultural influences. A multidisciplinary assessment including educational and clinical psychologists, social workers etc may be necessary in individual cases.

## Treatment monitoring (6 monthly)<sup>1</sup>:

- Height and weight – at Consultant clinics on centile chart
- Blood pressure and pulse rate – at Consultant clinics
- Full and differential blood counts – not carried out unless there appears to be problems (recurrent nose bleeds, bruising or infection). Any adverse effects are reversed on discontinuation.

In order to assess the effects of the drug on the child's emotional, physical or behavioural states there should be liaison with the school about the child's behaviour. The consultant will inform the GP how this will be done and by whom.

The GP should contact the consultant if patterns of behaviour deteriorate.

## Technology

- Methylphenidate is a short acting stimulant similar to amphetamines first used for hyperactive children in the USA in the 1960's.
- The drug will only work where hyperactivity and attention deficit are the presenting problems and not on behavioural problems such as oppositional type behaviour which may mimic ADHD.
- Treatment should be discontinued periodically, usually annually, by the consultant. The drug is stopped immediately and the child will be kept under review by the consultant with close liaison with the parents and the school.

## Audit / Survey (To be carried out by specialist clinic)

- Total number of patients assessed
- Number referred to Consultant
- Number of patients receiving treatment
- Are they being monitored correctly according to shared care protocol?
- Length of time drug used
- Evidence of benefit: increase in daily living abilities etc
- Length of treatment, number discontinued and reason for discontinuation

**This does not replace the SPC(s) which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.**

**Contact numbers for advice and support:**

Paediatric Consultants:	Dr B Zoritch	01932722126
	Dr W Nackasha	01932722764
Associate Specialist:	Dr M Potgieter	01932722126
ADHD Specialist Nurse:	Jane Brickell	01932722126
Medicines Information Frimley Park Hospital		01276 604744

**References:**

1. NICE technology Appraisal Guidance No 13 October 2000: Guidance on the use of Methylphenidate (Ritalin, Equasym) for attention deficit hyperactivity disorder (ADHD) in childhood
2. CCOHT: Meta analysis of the treatment of Attention Deficit Hyperactivity disorder 1999
3. Jadad AR, Boyle M, Cunningham C et al. Treatment of attention deficit hyperactivity disorder, Evid Rep Technol Assess (Summ) 1999 Nov:1-341. <http://www.ahcpr.gov> (In Evidence Based Medicine, Issue No 7. June 2002)
4. Charach A; Ickowica A & Schachar R. Stimulant treatment over five years: Adherence, Effectiveness and adverse effects. J Am Acad Child Adolesc Psychiatry 2004, 43: 559-567
5. Product specification, Concerta XL – [www.medicines.org.uk/searchresult.aspx?search=concerta](http://www.medicines.org.uk/searchresult.aspx?search=concerta) (accessed 11<sup>th</sup> June 2004)
6. DEC Methylphenidate in AD/HD 1998
7. Product specification, Ritalin – [www.medicines.org.uk/searchresult.aspx?search=ritalin](http://www.medicines.org.uk/searchresult.aspx?search=ritalin) (accessed 11<sup>th</sup> June 2004)
8. Product specification, Equasym – [www.medicines.org.uk/searchresult.aspx?search=equasym](http://www.medicines.org.uk/searchresult.aspx?search=equasym) (accessed 11<sup>th</sup> June 2004)
9. NICE Guideline 2008 – Attention Deficit Hyperactivity Disorder; Diagnosis and Management of ADHD in Children, Young People and Adults; National Clinical Practice Guideline Number 72; (September 2008).

Reason for Update: New		Prepared by:
Valid from:	Review date:	Approved by:
Version: 0.1	Supersedes version:	Approved by:
Page 1 of 1		