**SHARED CARE PROTOCOL**  
**AND INFORMATION FOR GPs**

<table>
<thead>
<tr>
<th><strong>Methylphenidate</strong></th>
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<tbody>
<tr>
<td><strong>Clinical indication:</strong> Children With Attention Deficit Hyperactivity Disorder (ADHD)</td>
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<tr>
<td><strong>Version 2: December 2009</strong></td>
</tr>
</tbody>
</table>

### Introduction

Attention-Deficit Hyperactivity Disorder (ADHD) is diagnosed if the three clinical features - inattention, over-activity and impulsiveness - have been present from an early age, persist in more than one situation (e.g. at home and in school) and impair function. The diagnosis must be made following a comprehensive assessment by an appropriate child psychiatrist and/or a paediatrician with special interest and training in this field. The assessment and management of this condition has been reviewed by SIGN Guideline No 52, June 2001. Drug therapy with methylphenidate is supported by NICE Technology appraisal No 98 (March 2006) and NICE Clinical Guideline 72 (September 2008). Medication is only one part of the package of care for children with ADHD which includes behavioural and educational interventions.

### Shared Care

As outlined in the NHS circular 1992 (Gen 11) when a consultant considers a patient’s condition is stable he/she may seek the agreement of the patient’s GP to ‘share’ the patient’s care. This protocol provides information on methylphenidate treatment guidelines for the shared commitment between the consultant and GP concerned. The shared agreement is voluntary and the general practitioner should be comfortable with the situation before agreeing to take over responsibility.

The patient should have received initial treatment from the psychiatrist/paediatrician, been shown to respond and the dosage stabilised before prescribing is transferred to the GP. Once the patient has been stabilised a further four-week supply will be prescribed by the psychiatrist/paediatrician to allow adequate time for information to be passed to their General Practitioner.

Where patients are continuing treatment with methylphenidate beyond 1 year, re-evaluation of the need for therapy by a specialist in the treatment of ADHD is mandatory.

### Indication for Therapy

Methylphenidate (Ritalin®, Equasym®, Medikinet®, Concerta®) is licensed as part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) when remedial measures alone prove insufficient. Treatment must be initiated under the supervision of a child psychiatrist and/or a paediatrician with special interest and training in this field. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10.

The drug is not licensed for children less than six years of age, as a result, this shared care protocol applies to children 6 years and above.
Preparations Available

<table>
<thead>
<tr>
<th>Preparations Available</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Equasym®, Medikinet®</td>
<td>5mg, 10mg, 20mg tablets</td>
</tr>
<tr>
<td>Ritalin®</td>
<td>10mg tablets</td>
</tr>
<tr>
<td>Concerta® XL</td>
<td>18mg, 27mg, 36mg M/R tablets</td>
</tr>
<tr>
<td>Equasym XL®</td>
<td>10mg, 20mg, 30mg M/R capsules</td>
</tr>
<tr>
<td>Medikinet XL®</td>
<td>10mg, 20mg, 30mg, 40mg M/R capsules</td>
</tr>
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Methylphenidate is a Schedule 2 Controlled Drug and is therefore subject to the regulations for controlled drugs in relation to handwriting requirements e.g. stating the quantity to be dispensed in both words and figures and also storage requirements.

Recommended Dosage and Administration

Standard Formulations (Ritalin®, Equasym®, Medikinet®)

Careful dose titration is necessary at the start of treatment with methylphenidate. The recommended starting daily dose is 5 mg once daily or twice daily (e.g. at breakfast and lunch), increasing if necessary by weekly increments of 5-10 mg in the daily dose according to tolerability and degree of efficacy observed.

If improvement is not observed after appropriate dosage adjustment the drug will be discontinued. The patient should have received at least one month’s treatment from the psychiatrist/paediatrician, been shown to respond and the dosage stabilised before prescribing is transferred to the GP. Once the patient has been stabilised a further 4-week supply will be prescribed by the psychiatrist/paediatrician to allow adequate time for information to be passed to their General Practitioner.

The maximum recommended dose for methylphenidate is 60mg (in two or three divided doses). In some children rebound hyperactivity may occur as the effect of the drug wears off in the evening. Dividing the doses to include an additional dose at bedtime may eliminate this difficulty.

As detailed in SIGN 52 & NICE CG 72, in individual cases some patients may benefit from higher doses than the maximum licensed dose due to the variable nature of the psychostimulant response.

Modified Release Formulations

Concerta® XL

The recommended starting dose of Concerta® XL for patients who are not currently taking methylphenidate, or for patients who are on stimulants other than methylphenidate, is 18mg once daily. Careful dose titration by the physician in charge is required in order to avoid unnecessarily high doses of methylphenidate. Dosage may be adjusted in 18mg increments to a maximum of 54 mg/day taken once daily in the morning. In general, dosage adjustment may proceed at approximately weekly intervals.

For patient converting from standard release methylphenidate to Concerta® XL –

Concerta® XL is roughly equivalent to three-times a day dosing with the immediate release formulation. The formulation is 22% immediate release and 78% extended release which gives maximum drug concentration after 1-2 hours, with peak plasma concentrations at 6-8 hours.
### Previous Methylphenidate Daily Dose

<table>
<thead>
<tr>
<th>Dose</th>
<th>Recommended Concerta® XL dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mg Methylphenidate three times daily</td>
<td>18 mg once daily</td>
</tr>
<tr>
<td>10 mg Methylphenidate three times daily</td>
<td>36 mg once daily</td>
</tr>
<tr>
<td>15 mg Methylphenidate three times daily</td>
<td>54 mg once daily</td>
</tr>
</tbody>
</table>

#### Equasym XL®

Equasym XL® helps provide ADHD symptom relief during the school day. Equasym XL® contains immediate and extended release methylphenidate at the ratio of 30:70. This gives peak plasma levels similar to immediate release methylphenidate to coincide with the start of the school day. Equasym XL® 20mg once daily is considered equivalent to 10mg twice daily of the immediate release formulation. Equasym XL® provides symptom relief for the time equivalent to the average school day whereas the effect of Concerta® XL lasts for up to 12 hours.

In those patients not currently taking methylphenidate, the starting dose for Equasym XL® is 10mg once daily in the morning before breakfast. Increasing gradually, if required.

Patients established on an immediate release methylphenidate hydrochloride formulation may be switched to the milligram equivalent daily dose of Equasym XL®.

#### Medikinet XL®

Medikinet XL should be taken in the morning with or after breakfast.

Medikinet XL consists of an immediate release component (50% of the dose) and a modified release component (50% of the dose). Hence Medikinet XL 10 mg yields an immediate-release dose of 5 mg and an extended release dose of 5 mg methylphenidate hydrochloride. The extended-release portion of each dose is designed to maintain a treatment response through the afternoon without the need for a midday dose. It is designed to deliver therapeutic plasma levels for a period of approximately 8 hours, which is consistent with the school day rather than the whole day. For example, 20 mg of Medikinet XL is intended to take the place of 10 mg at breakfast and 10 mg at lunchtime of immediate release methylphenidate hydrochloride.

In those patients not currently taking methylphenidate, the starting dose for Medikinet XL® is 10mg once daily in the morning with or after breakfast. Increasing gradually, if required.

Patients established on an immediate release methylphenidate hydrochloride formulation may be switched to the milligram equivalent daily dose of Medikinet XL®.

#### Cost

The following are cost estimates for treatment with methylphenidate at a moderate and maximum dose. Manufacturers’ equivalent doses are used for comparison between standard and long acting preparation. Costs are based on BNF 57.

<table>
<thead>
<tr>
<th>Brand</th>
<th>Dose</th>
<th>Cost per patient per year</th>
<th>Dose</th>
<th>Cost per patient per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>30mg daily</td>
<td>£209</td>
<td>60mg daily</td>
<td>£418</td>
</tr>
<tr>
<td>Ritalin®</td>
<td>30mg daily</td>
<td>£201</td>
<td>60mg daily</td>
<td>£402</td>
</tr>
<tr>
<td>Equasym®</td>
<td>30mg daily</td>
<td>£182</td>
<td>60mg daily</td>
<td>£364</td>
</tr>
<tr>
<td>Medikinet®</td>
<td>30mg daily</td>
<td>£180</td>
<td>60mg daily</td>
<td>£360</td>
</tr>
<tr>
<td>Concerta® XL</td>
<td>36mg daily</td>
<td>£485</td>
<td>54mg daily</td>
<td>£841</td>
</tr>
<tr>
<td>Equasym XL®</td>
<td>20mg daily</td>
<td>£360</td>
<td>60mg daily</td>
<td>£840</td>
</tr>
<tr>
<td>Medikinet XL®</td>
<td>20mg daily</td>
<td>£364</td>
<td>60mg daily</td>
<td>£877</td>
</tr>
</tbody>
</table>
Shared Care Responsibilities:

Aspects of care for which the Paediatrician and/or Psychiatrist are responsible

- Assessment and diagnosis of children with ADHD
- Initiation of therapy and supply of medicine for one further month after the dose has been stabilised.
- Patient monitoring - initially 3 monthly as a minimum, then 6 monthly in the longer term. This includes height, weight, blood pressure, heart rate and response to therapy
- Discontinuation - advising the GP when methylphenidate should be discontinued for children receiving the drug long-term. This will generally be during or after puberty. The specialist will provide necessary supervision and support during the drug discontinuation phase
- Updating the patient held monitoring sheet
- If methylphenidate is continued beyond adolescence then care should be transferred from Paediatric / Child and Adolescent Mental Health Services (CAMHS) to Adult Psychiatry Services.
- Continuing supply of methylphenidate for children under 6 years

Aspects of care for which the General Practitioner is responsible

- Prescribing methylphenidate once the patient is stabilised
- Cognisance should be given to quantities prescribed
- Liaison with the Paediatrician/Psychiatrists regarding any complications of treatment

Adverse Effects

The following adverse effects have been reported:
- Insomnia
- Decreased appetite
- Occasional abdominal pain, nausea and vomiting (alleviated with concomitant food intake)
- Headaches
- Emotional lability
- Temporary growth retardation may occur during prolonged therapy-monitor height and weight
- Changes in blood pressure and heart rate (usually increased) (rare)

Precautions and Contra-indications

- Methylphenidate is contra-indicated in patients with marked anxiety disorders, severe depression, psychosis, cardiovascular disease (including hypertension), hyperthyroidism and in patients with a tic disorder or Tourettes syndrome
- Methylphenidate should be used with caution in patients with a history of epilepsy

Drug Interactions

- MAOIs - Because of possible hypertensive crisis Equasym XL is contraindicated in patients being treated (currently or within the preceding 2 weeks) with non-selective, irreversible MAOIs
- Warfarin - may increase the anticoagulant effect
- Anticonvulsants – may increase plasma levels of phenobarbitone, primidone
- Alcohol may increase CNS effects of methylphenidate.

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