

## Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)

### SHARED CARE

**Drug: METHYLPHENIDATE**

**Protocol number: CV 42**

**Indication: ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD), HYPERKINETIC DISORDER (HKD)**

#### General Guidance

This protocol sets out details for the shared care of children, young people and adults taking **methylphenidate** and should be read in conjunction with the General Guidelines for Shared Care and the current NICE Clinical Guideline (No 72 Sep 2008). Methylphenidate is currently not licensed for treatment of adults with ADHD, however the need for treatment in adults is recognized in NICE guidelines. Patients needs to have this explained and their capacity to make informed decision about use of Methylphenidate needs to be documented. This is a secondary care responsibility. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition

#### Background

**Methylphenidate** is recommended as one of the options for use as outlined in NICE Guidance where drug treatment is deemed appropriate as part of a "comprehensive treatment programme" for children and adults with a diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD)

The decision regarding whether to use methylphenidate or an alternative drug should be based on the following:

- Presence of co-morbidities (e.g. tic disorders, Tourette's syndrome, epilepsy)
- Different adverse effects profiles of the drugs
- Specific compliance issues e.g. need to administer a mid-day dose at school or work
- Potential for drug diversion/misuse
- Preferences of child/adolescent/adult and/or parent/guardian based on clinical features of the patient.

When using methylphenidate consider:

- modified release preparations for convenience, their pharmacokinetic profile, improving adherence, reducing stigma (because the drug does not have to be taken at school) and reducing problems of storing and administering controlled drugs in schools
- immediate release preparations if more flexible dosing is required or during initial titration to determine correct dosing levels

Treatment with methylphenidate should only be initiated by an appropriately qualified healthcare professional with expertise in ADHD and should be based on a comprehensive assessment and diagnosis.

NICE recommends:

In Pre-school children - drug treatment is not recommended

In School age children and young people and adults with moderate ADHD and moderate impairment – drug treatment should be reserved for those with moderate impairment where non-drug interventions have been refused or where there are persisting significant impairment following parent- training/education programme or group psychological treatment

In School age children and young people and adults with severe ADHD (hyperkinetic disorder) and severe impairment – offer drug treatment first-line (also offer parents a group based training programme)

## **Responsibilities**

### **A. Consultant responsibilities**

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Comprehensive baseline assessment, initial prescribing and baseline and continued monitoring (see page 3,4)
3. The consultant must satisfy themselves that the patient or parent has the capacity to understand and to make an informed decision about the use of methylphenidate in an unlicensed situation and to document this in the records.
4. Initiate therapy following full discussion with the patient/carer of different treatment options, benefits and risks and need for contraception where appropriate.
5. Liaise with GP, School, and any other agency involved with the child/young person/adult, provide a comprehensive treatment programme for the patient, determine the frequency of specialist review following stabilisation and be aware of ongoing issues relating to prescribing when reaching young adulthood.

6. Titrate methylphenidate dose according to schedule below, adjusting dose as appropriate and undertake monitoring of clinical response and side effects.
7. When a GP positive response to SC has been received and patient has been stabilized send a letter to GP “handing over” the Shared Care of the patient to the GP.
8. Respond to any request from GP to review the patient due to adverse effects of therapy.
9. Report adverse effects of therapy to the Medicines and Health Care products Regulatory Agency (MHRA).
10. Advise the GP on continuing or stopping methylphenidate therapy following medical review of the patient and associated drug therapy
11. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action, i.e. stopping medication.

## **B. General practitioner responsibilities**

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe methylphenidate as part of the shared care agreement once patient is stabilised.
3. Monitor the general health of the patient.\*+
3. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
4. Act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

\*With children and young persons monitoring will normally be undertaken by the Secondary Care Health Professional. However if a GP becomes aware that a child is experiencing an adverse effect such as weight loss and does not have an imminent appointment with the Consultant Paediatrician or CAMHS, they should request that the appointment be expedited.

+ With adults the GP is to monitor blood pressure annually.

## **Dosage Regimen**

### **General principles**

Prescribers should be familiar with the pharmacokinetic profiles of all the modified-release and immediate-release preparations available for ADHD to ensure that treatment is tailored effectively to the individual needs of the child or young person or adult.

Prescribers should be familiar with the requirements of controlled drug legislation governing the prescription and supply of stimulants.

During the titration phase, doses should be gradually increased until there is no further clinical improvement in ADHD (that is, symptom reduction, behaviour change, improvements in education and/or relationships) and side effects are tolerable.

Following titration and dose stabilisation, prescribing and monitoring should be carried out under locally agreed shared care arrangements with primary care.

Side effects resulting from drug treatment for ADHD should be routinely monitored and documented in the person's notes.

If side effects become troublesome in people receiving drug treatment for ADHD, a reduction in dose should be considered.

Healthcare professionals should be aware that dose titration should be slower if tics or seizures are present in people with ADHD.

Using methylphenidate in children and young people and adults with ADHD:

- initial treatment should begin with low doses of immediate-release or modified-release preparations consistent with starting doses in the BNF
- the dose should be titrated against symptoms and side effects over 4–6 weeks until dose optimisation is achieved
- modified-release preparations should be given as a single dose in the morning
- different versions of modified-release preparations may not have the same clinical effect. To avoid confusion between these different formulations of methylphenidate, prescribers should specify the brand to be dispensed.
- immediate-release preparations should be given in two or three divided doses.

Careful titration by the specialist is required to determine the optimal dose level and timing. The usual starting dose of IR methylphenidate is 5mg once or twice daily (e.g. at breakfast and lunchtime) increasing if necessary by weekly increments of between 5mg and 10mg in the daily dose. The usual maximum (licensed) daily dose is 60mg, in divided doses. The drug should be discontinued if improvement of symptoms is not observed after appropriate dose adjustment.

Stimulant dose equivalents (mg)

IR-MPH	Xenidate XL	Equasym XL	Medikinet XL
10	-	10	10
15	18	-	15
20	-	20	20
30	36	30	30
-	-	-	
45	54	-	45
60	72*	60	60

IR-MPH: immediate-release methylphenidate; Xenidate XL, Equasym XL and Medikinet XL brands of modified-release methylphenidate (Xenidate XL is bioequivalent to Concerta XL)

\* Licensed up to 54 mg (in children)

NICE suggests that after review of poor response to treatment, and consultation with a tertiary or regional centre the dose of methylphenidate may be increased to 0.7mg/kg up to three times a day (or a total daily dose of 2.1mg/kg/day) – up to a maximum of 90mg/day for immediate release or the equivalent modified release dose.

Higher doses are used in a very small number of children.

Following an adequate treatment response, drug treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually. The review should include a comprehensive assessment of clinical need, benefits and side effects, taking into account the views of the child or young person, as well as those of parents, carers and teachers, and how these views may differ. The effect of missed doses, planned dose reductions and brief periods of no treatment should be taken into account and the preferred pattern of use should also be reviewed. Coexisting conditions should be reviewed, and the child, young person or adult treated or referred if necessary. The need for psychological and social support for the child, young person or adult and for the parents or other carers should be assessed.

### **Monitoring in Secondary Care**

\*for children and young persons monitoring will normally be undertaken by the Secondary Care Health Professional however if a GP becomes aware that a patient is experiencing an adverse effect such as weight loss and does not have an imminent appointment with the Consultant Paediatrician or CAMHS, they should request that the appointment be expedited.

#### Before treatment

Children and young people and adults with ADHD should have a full pre-treatment assessment, which should include:

- full mental health and social assessment
- full history and physical examination, including:
  - assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms
  - heart rate and blood pressure (plotted on a centile chart)
  - height and weight (plotted on a growth chart) (children and young people). Adults would not need monitoring of weight, unless there is clinical concern over weight loss
  - family history of cardiac disease and examination of the cardiovascular system
- an electrocardiogram (ECG) if there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on cardiac examination
- risk assessment for substance misuse and drug diversion (where the drug is passed on to others for non-prescription use).
- Enquiry about history of seizures or tics

The majority of young adults presenting with ADHD have a diagnosis made in childhood or adolescence and previous treatment documented in medical records. In the absence of documented diagnosis specialist assessment by a practitioner with special interest in ADHD is recommended prior to treatment.

#### During treatment:

NICE states that for people taking methylphenidate routine blood tests and ECGs are not recommended unless there is a clinical indication.

FBC or other blood tests only if clinically indicated (Stop treatment if WCC  $<4.0 \times 10^9/L$ )

Children and young persons.

Blood pressure, and heart rate should be monitored before and after each dose change and every 6 months. Sustained resting tachycardia, arrhythmia or systolic BP greater than 95<sup>th</sup> centile (or a clinically significant increase) measured on 2 occasions should prompt dose reduction and referral to a paediatrician.

Height should be monitored 3 monthly during titration phase and thereafter at 6 monthly intervals.

Weight should be measured at 3 and 6 months after the start of treatment, then 6 monthly thereafter.

These values should be plotted on a growth centile chart such as the Child Growth Foundation Chart (CGFC). This should be reviewed by the Secondary Care health professional responsible for treatment.

If the height/weight centile falls by space equivalent to the gap between two centile lines on the CGFC, ensure patient is seen by a Consultant Paediatrician or CAMHS- **please refer to the first paragraph in the 'monitoring in secondary care' section on page 4**

Adults

Blood pressure monitored annually. There is no need to monitor height and weight unless there is clinical concern of weight loss.

#### **Adverse effects**

- **Insomnia**- there may be difficulty in falling asleep ( $>10\%$ ). This may be due to the effect of Methylphenidate itself or its effect having worn off. The timing of the last dose may need adjustment
- **Decreased appetite**-this is common on initiation of therapy, but is usually transient
- **Weight loss- strategies to reduce weight loss or manage decreased weight gain include-** taking medication with or after food rather than before meals; eating additional meals or snacks early morning or late evening when

stimulant effects have worn off; obtaining dietary advice and eating high-calorie food of good nutritional value.

- **GI upset** (abdominal pain, nausea and vomiting) -usually mild and transient. Can be alleviated by concomitant food intake. If doesn't resolve, discontinue medication following consultation with specialist.
- **Growth retardation**- this may rarely occur. The effect is reversible on discontinuation of the medication. Consider a planned break e.g. during school holidays to allow catch up (or weekend drug holidays).
- **Haematological**- rarely the WBC may be reduced. This is reversed on discontinuation of the medication. Stop if WCC  $<4.0 \times 10^9/L$ .
- **Tics** If persist beyond a few days, specialist advice should be sought re: dose reduction or discontinuation of medication.
- **Cardiovascular** – tachycardia, palpitations, arrhythmias, changes in BP and heart rate (usually an increase) (see above)
- **Mental health problems** – commonly aggression, affect lability; uncommon – mood alteration/swings, suicidal ideation, hallucinations. Refer to specialist for advice
- **Seizures** – if exacerbated seizures in a child with epilepsy, or de novo seizures the medication should be discontinued immediately

**IF YOU SUSPECT AN ADVERSE EFFECT OR REACTION HAS OCCURRED PLEASE CONTACT THE SPECIALIST DEPARTMENT INITIATING THE MEDICATION**

### **Interactions**

Reported drug interactions include anticoagulants, anticonvulsants, phenylbutazone, tricyclic antidepressants, pressor agents, MAOI's, guanethidine. The dosage of some of these drugs may have to be reduced.

Alcohol may exacerbate the adverse CNS effect of psychoactive drugs, including Ritalin. It is therefore advisable for patients to abstain from alcohol during treatment.

### **Contraindications and warnings**

Methylphenidate should not be used for children or adults with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; and thyrotoxicosis. The drug is also contraindicated in patients who currently exhibit severe depression, anorexia nervosa, psychotic symptoms, history of aggression or suicidal tendency as it may worsen these conditions. Caution is advised in the use of the drug for patients with epilepsy and emotionally unstable patients, such as those with a history of drug or alcohol dependence. Use not recommended in children or adults with known cardiac abnormalities (sudden death has been reported). Should generally not be used in patients with severe hypertension. Methylphenidate increases heart rate and systolic and diastolic BP therefore caution is indicated in patients whose underlying condition might be compromised by increases in heart rate or blood pressure.

Should not be used in pregnancy unless clearly necessary (no adequate data on safety)

## **Special Recommendations**

Because the XENIDATE® XL tablet is nondeformable and does not appreciably change in shape in the gastrointestinal (GI) tract, it should not ordinarily be administered to patients with pre-existing severe GI narrowing (pathologic or iatrogenic) or in patients with dysphagia or significant difficulty in swallowing tablets.

Due to the prolonged-release design of the tablet, XENIDATE® XL 18mg & 36mg should only be used in patients who are able to swallow the tablet whole with sufficient liquid. The 54mg tablet is scored on both sides and can be divided into equal halves which must be swallowed whole with sufficient liquid.

Equasym XL and Medikinet XL capsules may be swallowed whole with the aid of liquids, or alternatively, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids, e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed.

(For further information on NICE guidance contact: [www.nice.org.uk](http://www.nice.org.uk)) For further information/ advice contact local specialist

**Reviewed May 2016**

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