Methylphenidate (Ritalin) for attention deficit hyperactivity disorder

Summary

- Diagnosis of attention deficit hyperactivity disorder (ADHD) requires comprehensive information about symptoms and commonly associated conditions. Developmentally inappropriate symptoms with significant impairment should exist in at least two settings (e.g. home, school).
- Methylphenidate and dexamphetamine are the psychostimulant drugs of choice to treat ADHD. They have equal efficacy and a similar range of adverse effects.
- Drug therapy should be combined with educational and psychosocial interventions to support the individual, the family and the school environment.
- Permission from State or Territory departments of health may be required to prescribe psychostimulants, separate to the authority required for PBS prescribing.
- At least annual clinical review is required to measure progress and assess the ongoing need for drug therapy.
- Be alert that the risk of diversion of psychostimulants to people other than for whom they are prescribed can be a problem.

PBS listing

Authority required

Methylphenidate 10 mg tablets can be used to treat attention deficit hyperactivity disorder in accordance with State/Territory law.

Requests to the HIC to increase the maximum quantity from 100 tablets with five repeats will be limited to a maximum of 200 tablets with four repeats per authority, to minimise use of methylphenidate at doses above those approved in the product information.[1]

(Note that long-acting Ritalin LA capsules are not PBS listed.)

Reason for PBS listing

Methylphenidate was recommended for listing by the Pharmaceutical Benefits Advisory Committee (PBAC) on a cost-minimisation basis compared with dexamphetamine sulfate, with methylphenidate hydrochloride 10 mg being equi-effective to dexamphetamine sulfate 5 mg.[2]

Place in therapy

Psychostimulants should be considered as first-line treatment for attention deficit hyperactivity disorder (ADHD).[3–5] They reduce core symptoms of inattention and hyperactivity/impulsivity.

Methylphenidate and dexamphetamine are considered to have equal efficacy and a similar range of adverse effects.[6–10] Up to 30% of individuals with ADHD will not tolerate or respond to the first psychostimulant used; thorough dose titration and trialling the alternative psychostimulant can improve the response to around 90%.[3,6,11,12]

Diagnosing ADHD must be comprehensive

Clinical presentation varies greatly between individuals, children and adults, and girls and boys. The core symptoms are inattention (difficulty concentrating), often but not always accompanied by impulsivity and hyperactivity (disorganised, excessive levels of activity).[3,13] Symptoms are developmentally inappropriate and cause functional impairment in daily life. Impairment must be demonstrated in at least two settings (e.g. home, school, clinic, work, socially).[4]

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Diagnosing ADHD is not synonymous with a positive response to medication.[5] Additional assessment of co-existing conditions is required as well as details on language, motor skills, emotional vulnerability and school function; family history of similar traits or disorders should be sought.[3,5]

It is advisable that a paediatrician, child psychiatrist or a paediatric neurologist experienced in assessing children with emotional and behavioural problems confirm the diagnosis of ADHD before drug treatment begins.[5,12]

ADHD in adults

Diagnosis of adult ADHD is controversial; a history of ADHD in childhood is generally agreed to be essential.[5,14,15] There is a wide range of presentations, co-morbidities, severities and outcomes. Psychostimulants are effective and prescribing is increasing[16–18], with other managements being used concurrently.[15]

Only authorised medical practitioners can prescribe methylphenidate

General practitioners are normally not permitted to initiate psychostimulant therapy. In some states (e.g. NSW), GPs may continue treatment, particularly in adults. Statutory regulations vary among States and Territories regarding methylphenidate prescribing; for example, in some States prescribers need to apply for permission to prescribe methylphenidate.

Contact the relevant State or Territory department of health (Table 1) for details on how to comply with the provisions of State or Territory law when prescribing methylphenidate.

Methylphenidate is a Schedule 8 controlled drug for which additional prescribing restrictions apply in most States and Territories (e.g. sole drug on prescription, maximum quantity in words and figures, prescriber's details in full and handwritten).

Table 1: State/Territory authorities to contact about methylphenidate prescribing

Tasmania Pharmaceutical Services Branch Department of Health and Human Services Tel: 03 6233 8011 Fax: 03 6233 3904	**South Australia** Public & Environmental Health Service Department of Human Services Tel: 08 8226 7110 Fax: 08 8226 7102
New South Wales Pharmaceutical Services Branch NSW Health Tel: 02 9879 3214 Fax: 02 9859 5165	**Queensland** Pharmaceutical Advisory Services Queensland Health Tel: 07 3234 1167 Fax: 07 3234 0773
Western Australia Pharmaceutical Services Branch Department of Health (WA) Tel: 08 9388 4980 Fax: 08 9388 4988	**Victoria** Drugs & Poisons Unit Department of Human Services Tel: 1300 364 545 Fax: 1300 360 830
Australian Capital Territory ACT Department of Health & Community Care Pharmaceutical Services, Population Health Division Tel: 02 6207 3974 Fax: 02 6205 0997	**Northern Territory** Poisons & Pharmacy Territory Health Services Tel: 08 8922 7035 Fax: 08 8922 7200

Always combine medication, school and psychosocial interventions

Cognitive, academic and social benefits vary and are highly individual. There is little evidence that medications for ADHD produce longer-term benefits on a child's academic performance.[11] Similarly, behavioural and psychosocial interventions are not well evaluated: results are inconclusive and require further research.[19] Problems measuring therapy effects in studies relate to the variety of behavioural rating scales available and a lack of understanding as to how these scales translate into clinically meaningful outcomes.

Despite a lack of firm evidence, it is generally recommended that treatment should be multimodal and consider simultaneous medication use, behaviour management, family knowledge about ADHD as well as counselling and support (e.g. respite, self-help groups), educational management, and specific developmental issues.[4,5,8]

A study of multimodal treatment of children with ADHD found that the effects of methylphenidate alone were equal to those of psychosocial intervention and methylphenidate combined. The combined group, however, achieved an equivalent degree of improvement with a significantly lower dosage of methylphenidate.[20] Striving for combined intervention with a lower dose of medication is preferable to higher-dose medication alone, as the likelihood of adverse drug effects is related to dosage.[4]

Family education about ADHD and guidance in therapy is useful in helping to develop more adaptive problem solving and family interactions. It is often based on working with the family as a group to improve communication and problem-solving skills, develop more effective methods of controlling behaviour and expressing emotion, and encourage new patterns of interaction.[5,21]

Educational interventions are classroom strategies designed to assist in overcoming learning difficulties and to promote consistency of management between home and school. Methods include teacher skills training, role plays and teacher assessment and observation.[5]

Dietary manipulation is not routinely recommended.[4,5] Individual food responses and avoidance may be significant in a minority of patients.

Review the ongoing need for drug therapy

Treatment and management of patients with ADHD should be reviewed regularly. A review should be conducted at least annually using the same parameters as for the initial diagnosis. Such a review should collect information from multiple sources and specifically evaluate any deterioration following significant interruptions to the medication regimen.[5]

Safety issues

Psychostimulants can cause a range of troublesome adverse effects, including anorexia and weight loss, abdominal pains, sleep disturbances, headaches, irritability and depressed mood.[3,10,21]

While retarded growth and weight loss are often cited as potential adverse effects of psychostimulants, there does not appear to be any significant long-term effect on height.[4–6,8] Weight and height should nonetheless be monitored.

ADHD is associated with tic disorders. Evidence now suggests stimulant medications do not necessarily precipitate tic disorders: these often wax and wane independent of stimulant use.[22] Treating the ADHD is often the main priority.[3] Nevertheless, caution is advised when using methylphenidate in patients with symptoms or a family history of tics or Tourette's syndrome.[6,8]

The possibility of adolescents sharing medication with peers who do not have ADHD has been reported and is always of concern.

Consult the *Australian Medicines Handbook* or Ritalin product information for more information about adverse effects.

Report suspected adverse reactions to the Adverse Drug Reactions Advisory Committee (ADRAC) on-line (www.tgasime.health.gov.au) or by using the 'Blue Card' distributed with the *Schedule of Pharmaceutical Benefits*. For information about adverse event reporting, see the Therapeutic Goods Administration website (www.tga.gov.au).

Dosing issues

The response to psychostimulants is commonly rapid and marked.[6] The child, parents, teachers and therapist can each nominate the main target symptoms. It is important to trial one medication at the maximum tolerated dose before declaring no benefit.[3]

Children 6 years and over should start with methylphenidate 5 mg 1–2 times daily, increasing to 3 times daily over 2 weeks.[3] Titrate the dose gradually (e.g. by 5–10 mg weekly up to 2 mg/kg/day) to a maximum dose of 60 mg/day.[8,12,23] Administering psychostimulants three times daily (early morning, mid-to-late morning, and mid-afternoon) sustains treatment effects more steadily at school and benefits homework or evening activities.[4] Methylphenidate should be discontinued if there is no benefit after one month of maximally tolerated treatment.[6,23]

Careful specialist supervision is required in children of preschool age with or without other developmental disabilities (e.g. autism) to optimise dosage.

Methylphenidate is absorbed faster when taken with food; administration should be standardised relative to food to promote a consistent effect.[6] It has been suggested that doses be given with or after food because of the anorectic properties of psychostimulants.[11]

Information for patients and parents

For more detailed information about methylphenidate, suggest or provide the Ritalin consumer medicine information (CMI) leaflet.

Reassure parents that, although some children show diminished growth rate and weight loss, long-term effects on height are generally not observed.

Reassure parents that psychostimulant therapy does not increase the risk of substance misuse; rather, it reduces the risk of substance misuse later in life.

Alert parents to the potential problem of diversion of psychostimulants to peers and others for whom the therapy is not prescribed. In adolescent patients, reasons why the medicine should not be given to others could be discussed.

Information suitable for patients and their families, including contact details for State-based ADHD support groups, is available from Health*Insite* at www.healthinsite.gov.au.

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Date prepared: June 2005

The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence.
Any treatment decisions based on this information should be made in the context of the clinical circumstances of each patient.