

5.10 METHYLPHENIDATE

Capsule containing methylphenidate hydrochloride 60 mg (modified release) Ritalin LA[®], Novartis Pharmaceuticals Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the listing of methylphenidate hydrochloride 60 mg modified release capsule (Ritalin[®] LA 60 mg), under the same conditions as the currently listed Ritalin LA strengths (10 mg, 20 mg, 30 mg and 40 mg).

2 Background

- 2.1 Methylphenidate hydrochloride 60 mg modified release capsule was TGA registered on 11 March 2016 for the treatment of attention deficit hyperactivity disorder (ADHD).
- 2.2 The TGA approved product information states that daily doses above 60 mg are not recommended for the treatment of ADHD in children and adolescents, and daily doses above 80 mg are not recommended for the treatment of ADHD in adults.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Requested listing

- 3.1 The submission requested the same restriction for Ritalin LA 60 mg as the existing listings for Ritalin LA on PBS.

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	DPMQ	Proprietary Name and Manufacturer	
METHYLPHENIDATE methylphenidate hydrochloride 60 mg modified release capsule, 30	NEW	1	30	5	\$ [REDACTED]	Ritalin LA 60 [®]	Novartis Pharmaceuticals Australia Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners (CTO) <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required – Telephone/Electronic
Indication: Attention deficit hyperactivity disorder
Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive AND Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events AND Patient must require continuous coverage over 8 hours

Administrative Advice:

Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Administrative Advice:

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

4.2 The PBAC noted and welcomed the input from individuals (18) and health care professionals (2) via the Consumer Comments facility on the PBS website. The comments highlight the positive impact of Ritalin LA on quality of life, the dosing convenience of a single capsule for patients currently receiving high doses, and cost saving to patients through reduced co-payments.

Economic analysis

4.3 The submission proposed an approved ex-manufacturer price (AEMP) of \$ [REDACTED], resulting in a dispensed price for maximum quantity (DPMQ) of \$ [REDACTED]. The proposed price is based on the AEMP of the 30 mg strength being [REDACTED]% of the proposed AEMP of the 60 mg strength. This is consistent with the pricing approach accepted by PBAC when Ritalin LA 10mg was recommended for listing at the March 2010 meeting.

Drug cost/patient/year: \$ [REDACTED]

4.4 The estimated drug cost per patient per year for Ritalin LA 60 mg was \$ [REDACTED] based on the proposed DPMQ and 12 scripts per year.

Estimated PBS usage & financial implications

4.5 The minor submission considered that the market for methylphenidate was stable and not likely to grow as a result of the proposed listing.

4.6 The submission considered that Ritalin LA 60 mg would substitute for Concerta® 54 mg, and that this substitution would result in an estimated net annual saving to the PBS of less than \$10 million. However, it is also likely that Ritalin LA 60 mg would substitute for the use of multiple existing lower strengths of Ritalin LA (such as patients using 2 x 30 mg capsules daily).

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC outcome

- 5.1 The PBAC recommended listing methylphenidate modified release capsules 60 mg (Ritalin LA 60 mg), under the same conditions as the currently listed Ritalin LA strengths (10 mg, 20 mg, 30 mg and 40 mg).
- 5.2 The PBAC acknowledged that listing a higher strength of Ritalin LA may benefit ADHD patients prescribed higher doses of methylphenidate, including older children and adults, but raised concerns about inappropriate and premature dose escalation.
- 5.3 The PBAC considered that the price proposed was consistent with previously accepted pricing methodology for higher strength formulations.
- 5.4 The PBAC noted that the estimated savings resulting from the listing were reasonable, and may have been underestimated when considering savings that may result from patients currently co-prescribed multiple lower strength capsules switching to a single 60 mg capsule.
- 5.5 The PBAC advised that Ritalin LA 60 mg is suitable for nurse practitioner prescribing as continuing therapy only, in line with existing listings for methylphenidate.
- 5.6 The PBAC advised that the Early Supply Rule should not apply as it does not apply to other methylphenidate listings.
- 5.7 The PBAC advised that, because Ritalin LA 60 mg is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over currently listed forms of Ritalin LA, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 5.8 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Add new strength:

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Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners (CTO) <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required – Telephone/Electronic/Emergency
Indication: Attention deficit hyperactivity disorder
Population criteria: Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive
AND
Clinical criteria: Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events
AND
Patient must require continuous coverage over 8 hours
Administrative Advice: Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.