



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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Dr Geraldine MacGibbon
Senior Therapeutics Group Manager
PHARMAC
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Dear Geraldine

Proposal to fund Melatonin 2mg modified-release tablets (Circadin)

We would like to add to our previous comments on the proposal for melatonin 2mg modified-release tablets to be discussed at the PTAC meeting in August 2014.

We are grateful that PHARMAC has gained an agreement with Aspen to fund melatonin for this group of children. We have taken the time to gain further information regarding the use of melatonin products in children. The NHS ONEL GPs and NELFT Shared Care Guidelines (attached) have good information on the use of CR Melatonin in children. On page 2, they refer to crushing tablets to administer to children who cannot swallow tablets or who require alternative doses to the tablets. Although the CR properties are no longer retained, the result will be similar to IR capsules currently available in NZ.

We understand that, as per other countries, Circadin® CR 2mg tablets are the only registered melatonin product in NZ and that PHARMAC is unlikely to approve an unregistered melatonin product. If this is the situation, the Paediatric Society of NZ would like to recommend that the approval for Circadin CR 2mg tablets is approved.

Extended Approval

We would like to see approval extended for primary sleep disorders and delayed sleep-phase syndrome in children with no learning difficulties and those with visual impairment. Placebo controlled trials¹⁻⁴ also demonstrate beneficial effects in these children and alternatives have less evidence for efficacy and more potential side effects⁵.

We would like clarification of what happens when adolescents turn 18 years of age and require melatonin for insomnia due to their neurodevelopmental disorders. Other options are often not appropriate. Melatonin will be funded on this proposal only to the age of 18 years.

In summary, we would like PHARMAC to consider the following:

1. Approve melatonin CR 2mg tablets for children
2. Extended approval of melatonin to include disorders mentioned above

3. Consider extending approval of melatonin for adults between 18-55 years with a neurodisability (continued supply for teenagers who have been taking approved melatonin)

We look forward to discussing this further with you if more clarification is needed.

Kind regards,



Louise McDermott
Chairperson
Pharmacists and Therapeutics SIG
Paediatric Society of NZ



Dr Janine Thomson
Chairperson
Developmental SIG
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References

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