



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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

On behalf of the Pharmacists and Therapeutics and Developmental Special Interest Groups of the Paediatric Society of New Zealand, we are providing feedback on the proposal to fund modified-release melatonin for children and adolescents with insomnia secondary to neurodevelopmental disorders.

There is still strong support amongst Paediatric Specialists in New Zealand for melatonin to be funded and they support this proposal for PHARMAC to fund melatonin 2mg modified-release tablets (Circadin®).

We would however like to also request a more appropriate presentation for children should one become registered. The slow-release tablets can be crushed which then act with immediate-release properties but for some children, other options may be more appropriate. We would like to see a 1mg dose or liquid become registered and funded in New Zealand.

If registration is not forthcoming from companies, then listing available melatonin preparations as Section 29 medicines with Special Authority (SA) approval would vastly improve access for vulnerable children with swallowing difficulties. There are 3mg capsules (Healthcare Logistics, Twinlab), 2mg capsules (Healthcare Logistics) and 1mg capsules (Life extension) as well as 1mg and 3mg tablets (Country Life, Healthcare Logistics, TwinLab and Worldwide Labs) currently available under Section 29. These capsules and tablets are currently prescribed but those children unable to take the slow-release tablets under this funding proposal, will be left at a disadvantage. If some of these Section 29 products could be made available with SA approval, it would certainly allow more children to have equity of care.

We note that the maximum dose is 6mg on this proposal but would welcome discussion about seeing this increased to 10mg under special authority. Several studies link to this dose and are listed at the end of this letter. This is also the maximum dose recommended in the New Zealand Formulary for Children. The recommendation is for melatonin 2-3mg daily up to 4-6mg daily is covered by this proposal but not to the recommended maximum of 10mg daily. Again, we would like to see the ability to have this increased dose made available, under SA approval if necessary.

Although we highlighted the concern that proposed funding stopped at 18 years, we understand that the decision by PTAC not to recommend the funding of melatonin for patients older than 18 years is based on funded alternatives for this group as well as no funding application. We would like to see approval widened for adolescents with neurodevelopmental disorders who are still require extensive care networks for their quality of life.

We would also like to see the proposal have widened criteria for children without neurodevelopmental disorders who have primary sleep disorders which have failed therapy of usual sleep hygiene and on the recommendation of a paediatrician.

Circadin® 2mg modified-release tablets are the only registered melatonin products available in New Zealand and to have these funded supports safe prescribing. We welcome this proposal to widen access to Circadin®2mg modified-release tablets and would like further input into the use of SA approval for several Section 29 formulations which would ensure equity of access to appropriate paediatric formulations for all children requiring melatonin.

We look forward to hearing from you in relation to this feedback.

Yours sincerely,



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This letter has support from:

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References relating to maximum doses:

- **Melatonin for sleep problems in children with neurodevelopmental disorders: randomised double masked placebo controlled trial** *BMJ* 2012;345:e6664 doi: 10.1136/bmj.e6664 (Published 5 November 2012)
- **Melatonin treatment of sleep–wake cycle disorders in children and adolescents** Paediatric sleep–wake cycle disorders treated with MLT: literature review *Developmental Medicine & Child Neurology* 1999, 41: 491–500

References relating children with chronic sleep onset insomnia

- **Evaluation of sleep, puberty and mental health in children with long-term melatonin treatment for chronic idiopathic childhood sleep onset insomnia** *Psychopharmacology* (2011) 216:111–120
- **Melatonin for Chronic Sleep Onset Insomnia in Children: A Randomized Placebo-Controlled Trial** *J Child Neurol* 2001;16:86–92