51 - Dose

Dose

Prescribing in children and adolescents CHAPTER 5 Adverse effects Many of the children who have received melatonin in RCTs and published case series had developmental problems and/or sensory deficits. The scope for detecting subtle adverse effects in this population is limited. Screening for adverse effects was not routine in all studies. In early published accounts, melatonin was reported to worsen seizures11 and exacerbate asthma.12,13 Other reported adverse effects included headache, depression, restlessness, confusion, nausea, tachycardia and pruritis.14,15 However, in more recent and larger placebo-controlled studies involving children with learning difficulty, autism and epilepsy,3,16–18 there were no excess adverse effects in the treatment group over placebo and, in particular, seizures were not worsened. A Cochrane review also found no worsening of seizure frequency in patients with epilepsy who were given melatonin.19 Melatonin has no detectable impact on puberty.20 Dose The cut-off point between physiological and pharmacological doses in children is less than 500mcg. Physiological doses (i.e. <500mcg) of melatonin may result in very high receptor occupancy. The doses used in RCTs and published case series vary hugely with between 500mcg and 5mg doses usually being used, although much lower and higher doses have been studied. In one large RCT, 18% of children seemed to respond to a 500mcg dose but others seemed to require much higher doses (12mg).18 Increasing doses above 5mg is likely to provoke the direct sedative effects of melatonin rather than its sleep phase-shifting properties. This might be necessary and helpful for some children with severe and bilateral brain injury. No response to 6–10mg Response Sleep hygiene Parent-led sleep behavioural interventions Melatonin: Use licensed product 2–5mg Consider use of 6–10mg if response poor Discontinue melatonin Identify and treat secondary causes Not effective Childhood insomnia in association with ASD or ADHD Continue at minimum effective dose Figure 5.3 Summary of recommendations in the treatment of insomnia.

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