

Appendix: Dose Modification Criteria [posted as supplied by author]

Stepped dose increases

At each home visit the RP will review the sleep and seizure diary and adverse events in order to make an overall assessment of treatment effect. If a dose increase is to be undertaken the following criteria should all be met:

- (i) absence of Serious Adverse Events
- (ii) a minimum of 5 of 7 days completed in the sleep diary
- (iii) no “significant increase”* in seizure activity (where applicable)
- (iv) child having received at least 5 of the possible 7 doses in the current week and
- (v) a) child not falling asleep within one hour of “lights off” or “snuggling down to sleep” at age-appropriate times for the child in three nights out of five **, and/or
b) child having less than 6 hours of continuous sleep in three nights out of five.

* Defined as a doubling in seizure activity over the preceding four weeks

** This will be the child’s usual bedtime based upon the family’s normal routine

If any of the criteria are not met, or if there is any doubt, the current dose should be maintained.

Dose reductions, interruptions or permanent discontinuation

The decision to reduce, interrupt, or discontinue trial therapy is at the discretion of the treating clinician. Doses may be reduced, interrupted or discontinued at any time during the trial period for reasons such as unacceptable adverse effects (e.g. unacceptable increase in daytime fatigue, unacceptable behavioural change, doubling in the number of seizures during the preceding four weeks, unacceptable increase in number or severity of headaches), intercurrent illness, development of serious disease or any change in the patient’s condition that justifies the modification of treatment in the clinician’s opinion.