National Institute for Health and Clinical Excellence

Clinical guideline: Epilepsy Update

PRE-PUBLICATION CHECK ERROR TABLE

Organisation	Order number	Section number in FULL guideline	Page number	ERROR REPORT	NCGC
United Kingdom Clinical Pharmacy Association	1			We would like to note that since the draft guideline was produced there is now new information on the pricing of levetiracetam which would allow more firm conclusions to be drawn.	Thank you for your comment, but this is not a factual error in the guideline.
RCN	2			Nurses caring for people with epilepsy were invited to carry out a pre-publication check on the above guideline. There is no further comment to add on this guideline on behalf of the Royal College of Nursing. Thank you for the opportunity to participate in this work.	Thank you for your comment.
UCB Pharma	3	Recommendation 87	211	*In recommendation 87, the reference at the bottom of the page states that the cost of 1500mg a day of levetiracetam in June 2011 is* ***£2.74****. This is true if the dose is 2x500mg tablets plus 2x250mg tablets (so four tablets in total making a daily dose of 1500mg).* *Most clinicians would seek to minimise the tablet burden so the most common regimen would be 2x750mg (only two tablets) which would cost* ***£2.97*** *for the 1500mg daily dose.* *UCB asks that the more common number is chosen (£2.97) or that the regimen details (2x500mg + 2x250mg=1500mg) are specified in order to*  Keppra dose regimen structure.xlsx *make the relative costings clear*	Thank you for your comment. This is not a factual error in the guideline. However, the GDG have considered this - proposal and disagree with the suggested change.
UCB Pharma	4	10.3.1 Introduction	150	The introduction seems to be missing some text. The first sentence ends with the reference, suggestion that a section of text outlining the classification of seizures has been omitted.	Thank you. This has been revised.
GlaxoSmithKl	5	Full	62 &	Retigabine should be mentioned under item 90 on pages 62 and 274 in	Thank you for your

ine UK			274	the full guidelines alongside its relevant comparators, as per NICE TA232. It is fair to acknowledge retigabine and TA232 at the beginning of section 4 in the updates (on page 56) but it should also be mentioned explicitly in its relevant position in the guidelines. This is necessary to ensure the position of use for retigabine in the clinical pathway in refractory focal epilepsy is fully appreciated by those referring to these guidelines.	comment. This is not a factual error in the guideline but please note that reference to Retigabine has been added to the relevant sections in both the NICE and full guidelines according to the process by which TA guidance is referenced in clinical guidelines.
GlaxoSmithKline UK	6	Full	General	The Association of British Neurologists, Epilepsy Action, Epilepsy Society, ILAE and UKCPA have all requested the inclusion of retigabine in the Epilepsy Clinical Guideline update, as per NICE TA232.	Thank you for your comment. This is not a factual error in the guideline but please note that reference to Retigabine has been added to the relevant sections in both the NICE and full guidelines according to the process by which TA guidance is referenced in clinical guidelines.
GlaxoSmithKline UK	7	NICE guidelines	General	In the abbreviated NICE clinical guidelines, section 1.9.3.6 (p27) hasn't been seen to be updated to include retigabine as per our previous stakeholder comments and as per TA232. This is necessary to ensure the position of use for retigabine in the clinical pathway in refractory focal epilepsy is fully appreciated by those referring to these guidelines.	Thank you for your comment. This is not a factual error in the guideline but please note that reference to Retigabine has been added to the relevant sections in both the NICE and full guideline according to the process by which TA guidance is referenced

					in clinical guidelines.
ViroPharma SPRL	8	10.15	441	**Current text in NICE guidance** *Where facilities for resuscitation are not immediately available, diazepam can be administered rectally or midazolam (unlicensed use) can be given in the buccal cavity.* **ViroPharma Comment:** Buccolam (midazolam oromucosal solution) is now a licensed medicine therefore please consider revising statement. Proposed wording "Where facilities for resuscitation are not immediately available Buccolam can be given into the buccal cavity or diazepam can be administered rectally. Buccal midazolam is now licensed and should appear before rectal diazepam in this statement which is also reflected in this guidance (page 464, recommendation 156) which refers to buccal midazolam as being first line treatment before rectal diazepam.	Thank you for your comment. This has been revised.
ViroPharma SPRL	9	Recommendation 156, section other considerations	464	**Current text in NICE guidance**: *"Buccal midazolam is at present unlicensed and its use is off label"*. – This statement is no longer correct see ViroPharma below: **ViroPharma Comment:** Buccolam (midazolam oromucosal solution) is now a licensed medicine, approved for use in paediatric patients from 3 months to less than 18 years, in 4 age specific pre-filled oral syringes. Full indication as per SmPC provided	Thank you for your comment. This has been revised.
ViroPharma SPRL	10	Recommendation 156, title heading	464	**Current text in NICE guidance:** *Administer buccal midazolam** **At the time of publication ([month year]), this drugs did not have UK marketing authorisation for this indication and/or population (please see appendix K for specific details about this drug for this indication and population). Informed consent should be obtained and documented.* **ViroPharma Comment:**	Thank you for your comment. This has been revised.

				This asterix in the above statement is no longer applicable to buccal midazolam as Buccolam is now a licensed medicine, approved by the EMA 05 Sept 2011. Suggest deletion of asterix in title.	
ViroPharma SPRL	10	Recommendation 158, title heading	466	**Current text in NICE guidance:** *"Depending on response to treatment, the person's situation and any personalised care plan call an ambulance particularly if:* *the seizure is continuing 5 minutes after the emergency medication has been administered"* **ViroPharma Comment:** Consistency of messaging may need consideration in that 5 minutes are referenced in this NICE guidance vs within 10 minutes in the Buccolam approved patient information leaflet, see below: Buccolam patient information leaflet (approved by the EMA) states "If the siezure does not stop within 10 minutes of giving Buccolam: You must telephone for an ambulance immediately. You must keep the empty oral syringe to give to the ambulance staff so that they know how much BUCCOLAM has been given. Do not give the patient another dose of BUCCOLAM	Thank you for your comment. This is not a factual error in the guideline. The GDG considered that 5 minutes is a pragmatic real life threshold that should be applied to the clinical situation in accordance with the evidence.