

## (S)AE Report

### ADDITIONAL INFORMATION / CLARIFICATION

<b>Product :</b>  LACOSAMIDE	<b><u>Contact information:</u></b>  <b>Reporter/Investigator :</b>		<b>Patient Safety Case ID :</b>  <b>Query N° :</b>
<b>Adverse Event type:</b>  CARDIAC	<b>Email :</b>  <b>CRO :</b> <b>Email :</b>	<b>FAX :</b>  <b>FAX :</b>	
<b>Patient initials:</b>	<b>Patient DOB :</b>	<b>Country:</b>	<b>If study:</b> <b>Study N°:</b> <b>CRF N°:</b> <b>Treatment N°:</b>
<b>Patient gender:</b>	<b>Patient age:</b>		
You reported that your patient presented a cardiac event (e.g. <i>“Prolongation of the PR interval”</i> ) while exposed to lacosamide. In order for UCB to better assess this case, could you kindly provide us with the following information?			
<b>Question</b>	<b>Reply (Reporter / Investigator)</b>		
Patient date of birth and initials (if not previously provided)			
Clinical symptoms which led to the diagnosis			
Onset date (DD-MMM-YYYY)			

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Physical examination findings (e.g.weight, blood pressure, heart rate)			

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Medical history, especially risk factors: -family history of premature ischemic heart disease or arrhythmia -obesity -sleep apnea syndrome -hypertension -hyperlipidemia -nicotine use -diabetes mellitus -cardiac disorder: eg valvular heart disease, heart failure, coronary artery disease -acute temporary cause: eg alcohol intake, cardiac or thoracic surgery, electrocution, myocardial infarction, pericarditis, myocarditis, pulmonary embolism, hyperthyroidism			

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Other non-cardiac relevant medical history			
Lacosamide dose and indication			
Lacosamide start date			
Lacosamide stop date (if applicable)			
Other suspect drug(s). Please include dose and start/stop date if applicable.			
Concomitant drug(s). Please include dose and start/stop date if applicable.			

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Was a baseline ECG performed? If so, please provide ECG date and tracings.			
Was an ECG done at the time of the event? If so, please provide ECG tracings.			
Was an echocardiography done? Please provide results.			
Was a Holter done? Please provide results.			
Was a specific atrial enlargement searched?			
Could you exclude any thromboembolic event?			

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Were lab tests performed? If so, please specify the tests performed. In particular, were the following tests performed: serum potassium, serum magnesium, serum ionized calcium, TSH and T4 levels? Please attach the lab reports with baseline values (if available) and with normal ranges, through the time of the patient's recovery.			
Other Tests/Investigations performed			
Treatment of the event.			
Action taken with lacosamide (stop date if applicable).			
Outcome of the event.			
Relationship to lacosamide (Related/Not related).			
Other Comments:			

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<b>Completed by :</b>		<b>Date :</b>	<b>Signature :</b>