

## Supplementary S2. Study period flow chart

Visit/Period																	
Day	D-1 (Optional)	D1 or D2															
Theoretical time		Pre-dose	T0h	T10min	T20min	T30min	T45 min	T1h	T1h30	T2h	T2h30	T3h	T4h	T6h	T8h	T10h	T10h+X
Inclusion/exclusion criteria		X															
Prior/concomitant medications		X															
Physical examination including buccal examination		X															X <sup>c</sup>
Hematology		X <sup>b</sup>															X <sup>c</sup>
Biochemistry		X <sup>b</sup>															X <sup>c</sup>
Pregnancy test (urine)		X <sup>b</sup>															
Admission	X	X															
Discharge																	X <sup>c</sup>
Randomization		X <sup>b</sup>															
Ondansetron premedication		X <sup>d</sup>															
Study Drug Administration			X														
Meals <sup>a</sup>													X				X <sup>b</sup>
12-lead ECG recording																	X <sup>c</sup>
Blood pressure and heart rate		X															X <sup>c</sup>
Blood sample for Pharmacokinetics		X		X	X	X	X	X	X	X	X	X	X	X	X	X	
AE collection		X															

<sup>a</sup>At D1 and D2, patients received a standardized lunch at T4h after the study drug administration. Lunch was given 10 minutes after blood sampling. At D1 only and in case of hospitalization, patients received a standardized dinner after the last blood sampling i.e., 10h to 12h after drug administration; <sup>b</sup>On D1 only; <sup>c</sup>On D2 only; <sup>d</sup>30 minutes before drug administration. D, day; ECG, electrocardiogram.