Seal or Varnish

Serious Adverse Reaction (SAE) Report Form



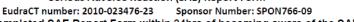
EudraCT number: 2010-023476-23 Sponsor Number: SPON766-09
Submit completed SAE Report Form within 24hrs of becoming aware of the SAE.
Secure fax number: 029 2068 7612 FAO: Seal or Varnish Trial Manager

Report Type:										
Details of participant affected by SAE										
School ID Participant ID Initials Date of Birth Gender M F										
Details of SAE (continue on separate sheet if necessary)										
Onset Date: Duration: Duration:										
Occurrence of Event reported by: Member of Dental Team Parent										
Date trial site aware of event:										
SAE outcome:										
Main event or reaction: Please state a single event or reaction										
Full description of event or reaction, including location event took place, body site, reported signs and symptoms and diagnosis, treatments received, actions taken. (Please include results of relevant test if appropriate): If event results in death, please confirm cause of death (or state N/A):										
The event is SERIOUS because it (tick as many as apply): Resulted in death Is or was life-threatening Resulted in hospitalisation Prolonged an existing hospitalisation Resulted in persistent or significant disability on incapacity Resulted in a congenital anomaly or birth defect Other event which required intervention to prevent any of the above outcomes										
Details of Investigational Medicinal Product(s) / Intervention										
Name of IMP(s) / Intervention / Inte										
NAME: Signature: Date:	_									

For office use only
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	Drug Dose (including units)	Route of administration (e.g oral, intravenous,etc)	Date first administered dd/mm/yyyy	Date & Time (24h clock) last administered or state ongoing	1		l (e.g. none eatment sto	
urther information re	elevant to ass	sessment (e.g medi	cal history, family	history, test results):				
L CONFIDENTIAL THAT TO	HE CONTENT							
I CONFIRM THAT II		S OF THIS FORM	ARE ACCURATE	AND COMPLETE				
			ARE ACCURATE	AND COMPLETE				
Name of person ma	aking report:		ARE ACCURATE	AND COMPLETE				
Name of person ma	aking report:		ARE ACCURATE	AND COMPLETE				
Name of person ma	aking report:		ARE ACCURATE		ATE:	DD	MM	YYYY
Name of person ma Telephone number Fax Number:	aking report:		ARE ACCURATE		ATE:	DD	MM	YYYY
Name of person ma Telephone number Fax Number:	aking report:		ARE ACCURATE		ATE:	DD	MM	YYYY
Name of person ma Telephone number Fax Number: PRINCIPAL INVESTI	GATOR'S SIG	GNATURE						
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Name of person ma Telephone number Fax Number: PRINCIPAL INVESTI Submit a copy of the SAE by secure	GATOR'S SIG	d form to SEWTU	J Seal or Varni:	D sh Trial Manager with	in 24h	rs of be	coming	aware
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CHIEF INVESTIGATOR / CLINICAL REVIE	WER DELEGATE ASSESSMENT Was the SAE drug related? 1= Definitely* 2= Probably* 3= Possibly* 4= Unlikely 5= Not assessable				Was the SAE listed as expected on the approved Reference Safety Information? Please circle				
Delton / Duraphat	e Hot ussessable				Yes		No		
COMMENTS:									
NAME:									
SIGNATURE:					DATE:	DD	MM	YYYY	
SEWTU ADMINISTRATION Date SAE form received at SEWTU: (day zero)	DD	MM	YYYY	Received by: (Print name)					
Date sent to clinical reviewer	DD	MM	YYYY	Clinical Reviewers (Print name)					
Reference Safety Information date:	DD	MM	YYYY						
EVENT CATEGORISATION: (Please tick)	SAE SAF 7 da	R day SU:							
For SUSARs only:									
Date reported to MHRA:	DD	MM	YYYY						
Date reported to Ethics:	DD	MM	YYYY						
Date reported to Sponsor:	DD	MM	YYYY						
Date reported to:	DD	MM	YYYY						
SEWTU STAFF SIGNATURE:					DATE:	DD	MM	YYYY	

Seal or Varnish SAE report form v1.0 18.03.2014 For office use only SAE number: