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**

SEAL OR VARNISH

Report Type: ☐ Initial ☐ Follow-up ☐ Final **Report Date:** ☐☐/☐☐/☐☐☐☐

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: ☐☐/☐☐/☐☐☐☐ End date: ☐☐/☐☐/☐☐☐☐ Duration: ☐☐☐☐☐☐☐☐

Occurrence of Event reported by: Member of Dental Team ☐ Parent ☐

Date trial site aware of event: ☐☐/☐☐/☐☐☐☐

SAE outcome: ☐ Resolved ☐ Ongoing ☐ Ongoing with sequelae ☐ Died ☐ Unknown

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

If other, please specify .....

Details of Investigational Medicinal Product(s) / Intervention

Name of IMP(s) / Intervention	Total dose administered	Date dose first administered dd/mm/yyyy	Date of last dose or state ongoing	Is the SAE related to the IMP / Intervention? 1= Definitely* 2=Probably* 3= Possibly* 4= Unlikely 5=Not assessable	Action taken (e.g. none, treatment reduced, treatment stopped)

NAME: _____ Signature: _____ Date: ☐☐/☐☐/☐☐☐☐

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Details of other treatment (including concomitant medication, surgery, radiotherapy, etc) Do not give details of therapy given to manage SAE.					
Treatment name	**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**	**Action taken** (e.g. none, treatment reduced, treatment stopped)

Further information relevant to assessment (e.g medical history, family history, test results):

I CONFIRM THAT THE CONTENTS OF THIS FORM ARE ACCURATE AND COMPLETE					
Name of person making report:					
Telephone number:					
Fax Number:					
PRINCIPAL INVESTIGATOR'S SIGNATURE		**DATE:**	DD	MM	YYYY

Submit a copy of the completed form to SEWTU Seal or Varnish Trial Manager within 24hrs of becoming aware of the SAE by secure fax to 029 2068 7612

Where complete information is not available at the time of the initial report, the principal investigator should submit a follow-up report as soon as possible.

FILE ORIGINAL IN TRIAL SITE FILE

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CHIEF INVESTIGATOR / CLINICAL REVIEWER 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				**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 Reviewer:** (Print name)			
Reference Safety Information date:	DD	MM	YYYY				
EVENT CATEGORISATION: (Please tick)	☐ SAE ☐ SAR ☐ 15 day SUSAR ☐ 7 day SUSAR						
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

For office use only
SAE number: .....