

NON-SERIOUS ADVERSE EVENT FORM

Patient concerned (trial number)

Name & address of podiatrist reporting event.

Date of event

Details of event

Please include details of: site, signs, symptoms, severity, onset and duration of reaction, batch number medicinal product, severity of event and any other information.

Action taken and outcome

Do you think the event is related to the trial treatment (50% salicylic acid or cryotherapy using liquid nitrogen)? (Please tick only ONE box)

Unrelated unlikely to be related possibly related probably related definitely related not able to assess if related

If the adverse event/reaction has resulted in any of the following you must complete a SAE form instead.

- Death
- A life-threatening risk (that is an immediate risk of death)
- Hospitalisation of patient or prolongation of existing hospitalisation
- Persistent or significant disability/incapacity
- Consists of a congenital anomaly or birth defect

Possible SAEs in the Verrucae trial. Please note that this is not an exhaustive list, if you suspect an event is serious, please contact the Trial co-ordinator –York Trials Unit. We would rather you erred on the side of caution and reported an event to us.

Suspected damage to underlying tissue eg tendon

Patient has died

Limb compromised:

Newly diagnosed diabetic: patient diagnosed as diabetic by GP during course of trial

Patient hospitalised

Signature _____ Date _____