**Supplementary Appendix 1. Adverse events reporting**

The study nurse screened for AEs of special interest during phone visit on Day 3, 4 and 8, using the checklist and entered the data into the patients’ electronic case report form. In the follow-up visit on Day 2 safety, hydration status and weight were recorded. On Day 3, 4 and 8 safety data were collected by the investigator via telephone contact with patients/legal guardians. Serious, unexpected, associated AEs were immediately reported to the IEC by the investigator and to the appropriate Health Authorities by the sponsor.