

Supplementary Table 4. Listing of serious adverse events from day 0 to study end, by system organ class and preferred term (overall safety set)

Serious adverse event, by system organ class and preferred term	Occurrence
Congenital, familial and genetic disorders	
Buried penis syndrome	1
Gastrointestinal disorders	
Enteritis	1
Infections and infestations	
Bronchiolitis	6
Croup infectious	1
Gastroenteritis	1
Hand-foot-and-mouth disease	1
Herpangina	1
Pharyngitis	1
Pharyngotonsillitis	1
Pneumonia	5
Pneumonia influenzal	1
Pneumonia parainfluenzae viral	1
Pneumonia respiratory syncytial viral	1
Pneumonia viral	1
Tonsillitis	2
Upper respiratory tract infection	2
Urinary tract infection	3
Viral infection	1
Injury, poisoning, and procedural complications	
Contusion	1
Ligament rupture	1
Tendon injury	1
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	
Cholesteatoma	1
Nervous system disorders	
Seizure	1