



## \*EXPECTED SAEs

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|--------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| • Anaemia                                                                                                                      | • Non-iatrogenic meningitis  |
| • Clinically significant intracranial abnormality on cranial ultrasound scan – intracranial haemorrhage or white matter injury | • Necrotising enterocolitis  |
| • Chronic lung disease/Broncho pulmonary dysplasia                                                                             | • Patent ductus arteriosus   |
| • Coagulopathy requiring treatment                                                                                             | • Pneumothorax or air leaks  |
| • Death                                                                                                                        | • Pneumonia                  |
| • Establishment of enteral feeding                                                                                             | • Pulmonary haemorrhage      |
| • Failed LP, or infection, resulting in prolonged hospitalisation                                                              | • Pulmonary hypertension     |
| • Hyperbilirubinemia (jaundice)                                                                                                | • Respiratory failure        |
| • Hypoglycaemia                                                                                                                | • Retinopathy of prematurity |
| • Hypoxic ischaemic encephalopathy                                                                                             | • Seizures                   |
| • Low sodium level/hyponatremia                                                                                                | • Sepsis/infection           |
|                                                                                                                                | • Thrombocytopenia           |
|                                                                                                                                | • Hypotension                |