

Serious Adverse Reaction [SAR]

An adverse drug reaction (ADR) is called serious if at any dose it:

- results in death,
- is life-threatening (at risk of death at the time of the adverse event, not an event which 'could' hypothetically have caused death if it were more severe),
- requires hospitalisation or extension of existing inpatients' hospitalisation,
- results in a persistent or significant disability or incapacity, or
- is a congenital anomaly or birth defect.