ID:_____ Initialer:_____ Dato:_____ Tester:_____

# SAE REPORT FORM

| SERIOUS ADVERSE EVENT INFORMATION | | | | | |
|---|---|---|---|---|---|
| **1. Report Type**<br>☐ Initial<br>☐ Follow-Up | **2. Date of Birth**<br>dd mm yyyy | **3. Age** | **4. Sex**<br>☐ male<br>☐ female | **5. Height**<br>cm | **6. Weight**<br>kg |

**7. Onset of First Signs/Symptoms of SAE**

dd mm yyyy

| **8. Serious Adverse Event(s) in medical terms** (diagnosis if possible) | Expedited Reporting Criteria<br>**9. Check all appropriate to event** |
|---|---|
| ----------<br>Case description of the above SAE (include related signs, symptoms, duration, treatment/outcome and suspected cause of the SAE) (continue on p. 3 – section 21 if more space is required) | ☐ Patient died on<br>dd mm yyyy<br>☐ Life-threatening<br>☐ Involved or prolonged inpatient hospitalisation<br>☐ Results in persistent or significant disability/incapacity<br>☐ Congenital anomaly or birth defect |

## HISTORY

**10. Patient's past medical history** (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

## DRUG INFORMATION

| **11. Drug given & dose before onset of SAE** | **12. Last visit documented in CRF before onset of SAE** |
|---|---|
| **PREDNISOLONE**<br>Total dose ___.___ – ____.___ mg | dd mm yyyy |

**13.Study drug**

Date and time of last given medication: dd mm yyyy ___ h ___ min [24:00]

Has the study drug been discontinued? ☐ yes → discontinued and given again: ☐ yes ☐ no

☐ no → dose reduction: ☐ yes ☐ no

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## DRUG INFORMATION

**14. Time elapsed between drug administration and onset of first signs/symptom of SAE**

└┴┘ minutes/hours/days/months (delete as applicable)

**15. Concomitant drug(s) relevant to the SAE** (exclude therapy to treat SAE)

| Drug name(s) | Dose / Route | Unit / Schedule | Date / Time started | Cont. 0 = no 1 = yes | If no, please insert date / time discontinued | Reason for use |
|---|---|---|---|---|---|---|
| | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |
| | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |
| | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |

**16. Comments** (if adverse event is considered to be caused by a co-medication, please note here)

**17. Test/Laboratory findings** (enter only those findings necessary for SAE diagnosis or course description)

| | Test/Lab Name | Unit | Date / Time | Value | Date / Time | Value |
|---|---|---|---|---|---|---|
| 1 | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |
| 2 | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |
| 3 | | | dd mm yyyy<br>h min [24:00] | | dd mm yyyy<br>h min [24:00] | |

**18. Comments on test/laboratory findings**
(If the SAE is a laboratory finding, enter comments on clinical findings and/or treatment in field 8)

# SAE REPORT FORM

**19. Outcome of the Patient/SAE**

☐ Completely recovered - Date of recovery:

dd mm yyyy

☐ Recovered with sequelae

☐ Condition improving

☐ Ongoing - condition still present and unchanged

☐ Condition deteriorated

☐ Death → Cause of death:

Autopsy: ☐ yes ☐ no

**20. Assessment of causality** (relationship to study drug)

☐ Unrelated

☐ Probable

☐ Unlikely

☐ Definite

☐ Possible

☐ Not assessable

**21. For additional information**

**TREATING INVESTIGATOR/REPORTING DATE**

| **22. Name & Signature of the Investigator** | **23. Reporting date** |
|---|---|
| _____<br>Name (First/Last name) & Signature | dd mm yyyy |