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| **Please send this form to Actelion Drug Safety department within 24 hours****by fax no:  +41 (0) 61 565 6490 or e-mail:** **DrugSafetyCH@actelion.com****Or report it to local representative Medis Adria d.o.o.:** (Tel.: +385 (0)1 2303 446; Fax.: +385 (0)1 2303 447; E-mail: **drug.safety@medisadria.hr** ) |
|  |
| **For any question or additional information you may call: +41 (0) 61 565 6695** |

|  |  |  |
| --- | --- | --- |
| **For Sponsor Use Only:** Information received by: |       | [ ] Initial  |
|  Date received: |       | [ ] Follow-up #       |

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| Reporter Information |
|  |
| Name of the person completing the form (if not the primary reporter):  |       |  |
| **Primary reporter’s name** |       |  |
| **Primary reporter’s contact details** |  |  |
| Telephone number: |       |  |
| Fax: |       |  |
| E-Mail: |       |  |
| Name of Institution: |       |  |
| Postal Code: |       |  |
| Address: |       |  |
| City: |       |  |
| Country: |       |  |
| Date of report (DD/MMM/YYYY): |    | / |       | / |       |  |
| **Reporter also sent report to country’s regulatory agency?** | [ ]  | Yes | [ ]  | No | [ ]  | Unknown |
| **Is the patient enrolled in DUO-Registry or** **Compassionate Use/Named Patient Program?** | [ ]  | DUO | [ ]  | Compassionate Use/Named Patient | [ ]  | InvestigatorInitiated Study |
| **If patient is enrolled in DUO-Registry, please provide:**  |
| Centre identifier number:       |
| Patient Identification Number:       |
|  |
|  |
| Patient Information |
|  |
| Patient initials (specify first, middle, last): |       |  |
| Date of birth (DD/MMM/YYYY): |    | / |       | / |       |  |
| Gender (Female; Male): |       |  |
| Body weight: |       | kg  |
| Height: |       |  cm |
| Indication for Tracleer use: |       |  |
| Additional details on indication: |       |  |
|  |

1. **Adverse event**

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| --- |
| **Adverse event 1**  |
|  |
| **Main adverse event/diagnosis:**If no diagnosis, provide most relevant or main sign/symptom |        |  |
| Date of onset (DD/MMM/YYYY): |    | / |       | / |       |  |
| Date of resolution of event (DD/MMM/YYYY): |    | / |       | / |       |  |
|  |
| Details of Event 1 |
|  |  |
| Suspected relationship to Tracleer? | [ ]  Yes | [ ]  No | Outcome? (status at time of report) |
| **Does the event meet any of the seriousness criteria listed below?** | [ ]  Yes | [ ]  No | Resolved with sequelae | [ ]  |
| **Please tick all that apply, or leave blank if non-serious:** | Resolved without sequelae | [ ]  |
| Death | [ ]  | Unknown/Lost to Follow-up | [ ]  |
| Life-Threatening | [ ]  | Death | [ ]  |
| Disability | [ ]  | Not resolved | [ ]  |
| Congenital Anomaly | [ ]  |  |
| Hospitalization | [ ]  New [ ]  Prolonged |  |
|  Admission date (DD/MMM/YYYY) |    | / |       | / |       |  |  |
|  Discharge date (DD/MMM/YYYY) |    | / |       | / |       |  |  |
| Medically Significant | [ ]  |  |
| Intervention required to prevent one of the above | [ ]  |  |
|  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Patient initials |        | Gender: |       | Year of Birth: |      |  |

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| --- |
| Adverse Event 2  |
|  |
| **Main adverse event/diagnosis:**If no diagnosis, provide most relevant or main sign/symptom |        |  |
| Date of onset (DD/MMM/YYYY): |    | / |       | / |       |  |
| Date of resolution of event (DD/MMM/YYYY): |    | / |       | / |       |  |
| Details of Event 2 |
| Suspected relationship to Tracleer? | [ ]  Yes | [ ]  No | Outcome? (status at time of report) |
| **Does the event meet any of the seriousness criteria listed below?** | [ ]  Yes | [ ]  No | Resolved with sequelae | [ ]  |
| **Please tick all that apply, or leave blank if non-serious:** | Resolved without sequelae | [ ]  |
| Death | [ ]  | Unknown/Lost to Follow-up | [ ]  |
| Life-Threatening | [ ]  | Death | [ ]  |
| Disability | [ ]  | Not resolved | [ ]  |
| Congenital Anomaly | [ ]  |  |
| Hospitalization | [ ]  New [ ]  Prolonged |  |
|  Admission date (DD/MMM/YYYY) |    | / |       | / |       |  |  |
|  Discharge date (DD/MMM/YYYY) |    | / |       | / |       |  |  |
| Medically Significant | [ ]  |  |
| Intervention required to prevent one of the above | [ ]  |  |
|  |  |

1. **Death (if applicable)**

|  |
| --- |
|  |
| If death occurred please specify date (DD/MMM/YYYY): |    | / |       | / |       |  |
| Cause of death: |       |
| Was an autopsy performed? | [ ] No | [ ]  Yes - If Yes, please provide a copy of the autopsy report |

1. **To be completed in case of increased liver function tests**

If attaching additional documents to this report, please indicate by ticking Yes **[ ]**  No **[ ]**

 (Please mask the patient’s name in any additional documents.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Laboratory Test** | **Baseline**     /     /     dd/mm/yyyy**Value** | **First Elevation**     /     /     dd/mm/yyyy**Value** | **Peak Elevation**     /     /     dd/mm/yyyy**Value** | **Follow-up values**      /     /     dd/mm/yyyy**Value** | Reference Range**ULN units** |
| **ALT (SGPT)** |       |       |       |       |       |
| **AST (SGOT)** |       |       |       |       |       |
| **Alkaline Phosphatase** |       |       |       |       |       |
| **Bilirubin (Total)** |       |       |       |       |       |
| **Bilirubin (Direct)** |       |       |       |       |       |
| **Did the patient experience any clinical signs of liver injury?** | [ ]  No  | [ ]  Yes | **If yes, please specify:** |       |
|  |

1. **Concomitant Medications**

List all concomitant medications taken at time of event.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Trade Name orGeneric Name | **Indication** | Start date | **Stop date** | **Tick if suspected of causing event(s)?** |
| DD | / | MMM | / | YYYY | DD | / | MMM | / | YYYY |
|        |       |    | / |       | / |       |    | / |       | / |       | [ ]  |
|       |       |    | / |       | / |       |    | / |       | / |       | [ ]  |
|       |       |    | / |       | / |       |    | / |       | / |       | [ ]  |
|       |       |    | / |       | / |       |    | / |       | / |       | [ ]  |

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| Patient initials |        | Gender: |       | Year of Birth: |      |  |

###### Tracleer Information

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| --- |
|  |
| Start date of Tracleer (DD/MMM/YYYY): |       |  |
| Initial dose & frequency of Tracleer: |       | mg |  | Times per day |
|  |
| Up-titration of Tracleer (DD/MMM/YYYY): |       |  |
| Up-titration dose & frequency: |       | mg |  | Times per day |
|  |
| Dose & frequency of Tracleer at time of event: |       | mg |  | Times per day |
|  |
| Batch no.: |       |  Expiry date (MMM/YYYY):  |       | / |       |  |
| **What was the action taken regarding Tracleer?** |
| **None** (continued at the same dose and frequency)  | [ ]  Please proceed to the next section. |
| **Permanently discontinued:** | [ ]  | Date: |    | / |       | / |       |  |
| **Dose and/or frequency reduced:** | [ ]  | Date: |    | / |       | / |       |  |
|  Reduced dose and/or frequency: |       | mg |  | Times per day |
|  |  |
| **Temporarily interrupted:** | [ ]  | Date: |    | / |       | / |       |  |
| **Not applicable** (if patient not on drug at time of the event): | [ ]  |
| **Unknown:** | [ ]  |
| If Tracleer was reduced, interrupted or discontinued did the event(s) improve or resolve (i.e.: abate)? | [ ]  | Yes | [ ]  | No | [ ]  | Unknown |
| If Tracleer was either reduced, interrupted or discontinued, please indicate the event(s) leading to this action:  |       |  |
| If Tracleer was reintroduced please specify date (DD/MMM/YYYY): |    | / |       | / |       |  |
|  Start dosage and frequency: |       | mg |  | Times per day |
| Did the event(s) reoccur upon reintroduction? | [ ]  | Yes | [ ]  | No | [ ]  |  Unknown |
| If Yes, was Tracleer discontinued thereafter? | [ ]  | Yes | [ ]  | No |
| If Yes, please specify date of discontinuation: |    | / |       | / |       |  (DD/MMM/YYYY) |
|  |

1. Relevant History

Please document any significant medical history that is considered **relevant** to the reported events.

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|       |

1. Event Narrative

Please complete a short description for the event(s), sequence of symptoms onset, time course, treatment therapies response and diagnosis.

|  |
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|       |

1. Reporter Information

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|  |
| Name and position of person completing this form: |       |
| Signature: |       | Date:  |      /     /      (DD/MMM/YYYY) |
|  |