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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**](mailto: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**](mailto:drug.safety@medisadria.hr) ) |
|  |
| **For any question or additional information you may call: +41 (0) 61 565 6695** |

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

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| Reporter Information | | | | | | | | | | | | | | | | |
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| 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 |  | Investigator  Initiated Study | |
| **If patient is enrolled in DUO-Registry, please provide:** | | | | | | | | | | | | | | | |
| Centre identifier number: | | | | | | | | | | | | | | | |
| Patient Identification Number: | | | | | | | | | | | | | | | |
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| Patient Information | | | | | | | | | | | | | | | | |
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| 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: |  | | | | | | | | | | | | | |  |
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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 |  | | | | | | | |  | |
|  | | | | | | | | |  | |

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| 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 |  | | | | | | | | |  | |
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1. **Death (if applicable)**

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| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
| 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.)

|  |  |  |  |  |  |  |  |  |
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| **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 or  Generic 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) |
|  | | | |