*Please complete and forward this form to Biotest AG Corporate Drug Safety, Landsteinerstr. 5, 63303 Dreieich – phone: +49 6103 801 756; fax: +49 6103 801 854 or* [*drugsafety@biotest.com*](mailto:drugsafety@biotest.com)

A privacy notice in relation to the personal data collected on this form is available at the Biotest website ([www.biotest.com](http://www.biotest.com)) under ‘*contact’* tab and by clicking on ‘*Reporting of suspected adverse drug reactions’*.

|  |  |
| --- | --- |
| Reporter name: |  |
| Address: |  |
| E-mail |  |
| Phone number |  |
| **If healthcare professional, state qualification**  Physician  Pharmacist  Care giver  Others, please state: | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Patient Data** | | | | | | | | | | | | | | | | | |
| Initials | Male  Female  Diverse | | | | | | | | Age | | | Height (cm) | | | | | Weight (kg) |
| Pregnancy  No  Yes  Unknown | | | | | If yes, estimated date of delivery (DDMMMYYYY): | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | |
| **Biotest Product** | | | | | | | | | | | | | | | | | |
| Suspect drug | | | | | Reason for treatment | | | | | | | | | Batch number | | | |
| Date of first administration | | | | | Last administration before the event | | | | | | | | | Temperature of infusion (°C) | | | |
| Duration of drug administration (unit) | | | | | Total volume infused (ml) | | | | | | | | | Rate of infusion (ml/60min) | | | |
|  | | | | |  | | | | | | | | |  | | | |
| **Suspected Reactions** | | | | | | | | | | | | | | | | | |
| *Brief description of the effects/side effects/interactions, including any information relevant to the circumstances of this reaction, medication error etc.* | | | | | | | | | | | | | | | | | |
| Reaction    There is a causal relationship between the drug and the ADR  There is no causal relationship between the drug and the ADR | | | | | | | | | | Treatment given / action taken: | | | | | | | |
| Start date reaction (DDMMMYYYY) | | | | Duration of reaction | | | | | | Outcome of reaction  Recovered, on (DDMMMYYYY)  Recovering  Not yet recovered  Rec. with sequelae  Fatal  Unknown | | | | | | | |
| Did similar reactions occur in this patient before?  No  Yes  If yes, related to similar drugs?  No  Yes  If yes, please specify | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **Seriousness** | | | | | | | | | | | | | | | | | |
| Drug discontinued  No  Yes  Dose reduced/infusion rate reduces (please specify)  Improvement of patient  No  Yes  Drug re-administered?  No  Yes  If yes, did the reaction reappear?  No  Yes | | | | | | | Do you consider the reactions serious (at least one of the below listed criteria fulfilled?)  No  Yes  If yes, please indicate which seriousness criteria apply (multiple possible).  Fatal  Immediately life threatening  Patient hospitalized (overnight) / hospitalization prolonged  Persistent or significant disability / incapacity  Congenital anomaly or birth defect  Medically significant – provide details  *(e.g. events that do not meet the standard criteria for seriousness, but based on medical judgment are considered serious as they may jeopardize the patient and may require medical or surgical intervention to prevent the event meeting the standard criteria for seriousness)*: | | | | | | | | | | |
| If seriousness is fatal  Date of death (DDMMMYYYY):  Cause of death:  Autopsy:  No  Planned Date:  Yes Date:  If yes, please provide autopsy report. | | | | | | |
|  | | | | | | |  | | | | | | | | | | |
| **Any other drugs used over this period?** | | | | | | | | | | | | | | | | | |
| None  Unknown | | | | | | | | | | | | | | | | | |
| Drug | | | Daily Dose | | | | | Route | | | Dates / duration of treatment | | | | Reason for treatment | | |
|  | | |  | | | | |  | | |  | | | |  | | |
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| **Relevant medical history** | | | | | | | | | | | | | | | | | |
| Description | | | | | | Start date  (DDMMMYYYY) | | | | | | | End date  (DDMMMYYYY) | | | Continuing? | |
|  | | | | | |  | | | | | | |  | | | No  Yes | |
|  | | | | | |  | | | | | | |  | | | No  Yes | |
|  | | | | | |  | | | | | | |  | | | No  Yes | |
| **Allergies** | | No  Yes | | | | If yes, please specify | | | | | | | | | | | |
| **IgA deficiency** | | No  Yes | | | | If yes, please specify | | | | | | | | | | | |

|  |  |  |
| --- | --- | --- |
| The local health authority was notified? | No  Yes | If yes, state which authority? |

**SIGNATURE** **DATE**

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS FORM.